Eucreas® 50 mg/1000 mg film-coated tablets

(vildagliptin/metformin hydrochloride)

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
* Keep this leaflet. You may need to read it again.
* If you have any further questions, ask your doctor, pharmacist or nurse.
* This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
* If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Eucreas 50 mg/1000 mg film-coated tablets but will be referred to as Eucreas throughout the leaflet. Please note that the leaflet also contains information about another strength of this medicine, Eucreas 50 mg/850 mg film-coated tablets.

What is in this leaflet

1 What Eucreas is and what it is used for

The active substances of Eucreas, vildagliptin and metformin, belong to a group of medicines called “oral antidiabetics”.

Eucreas is used to treat adult patients with type 2 diabetes. This type of diabetes is also known as non-insulin-dependent diabetes mellitus. Eucreas is used when diabetes cannot be controlled by diet and exercise alone and/or with other medicines used to treat diabetes (insulin or sulphonylureas).

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals. Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

How Eucreas works
Both active substances, vildagliptin and metformin, help to control the level of sugar in the blood. The substance vildagliptin works by making the pancreas produce more insulin and less glucagon. The substance metformin works by helping the body to make better use of insulin. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes.

2 What you need to know before you take Eucreas

Do not take Eucreas
* if you are allergic to vildagliptin, metformin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to any of these, talk to your doctor before taking Eucreas.
* if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see “Risk of lactic acidosis” below) or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
* if you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing which could be a sign of heart problems.
* if you have severely reduced kidney function.
* if you have a severe infection or are seriously dehydrated (have lost a lot of water from your body).
* if you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye). Please also see information about this in section “Warnings and precautions”.
* if you have liver problems.
* if you drink alcohol excessively (whether every day or only from time to time).
* if you are breast-feeding (see also “Pregnancy and breast-feeding”).

Warnings and precautions
<u>Risk of lactic acidosis</u>
Eucreas may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Eucreas for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Eucreas and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include:
* vomiting
* stomach ache (abdominal pain)
* muscle cramps
* a general feeling of not being well with severe tiredness
* difficulty in breathing
* reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor promptly for further instructions if:
* You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
* You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

Eucreas is not a substitute for insulin. Therefore, you should not receive Eucreas for the treatment of type 1 diabetes.

Talk to your doctor, pharmacist or nurse before taking Eucreas if you have or have had a disease of the pancreas.

Talk to your doctor, pharmacist or nurse before taking Eucreas if you are taking an anti-diabetic medicine known as a sulphonylurea. Your doctor may want to reduce your dose of the sulphonylurea when you take it together with Eucreas in order to avoid low blood glucose (hypoglycaemia).

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Eucreas. Should these occur, you should promptly consult your doctor.

If you need to have major surgery you must stop taking Eucreas during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Eucreas.

A test to determine your liver function will be performed before the start of Eucreas treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

During treatment with Eucreas, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or have worsening renal function.

Your doctor will test your blood and urine for sugar regularly.

Children and adolescents
The use of Eucreas in children and adolescents up to 18 years of age is not recommended.

Other medicines and Eucreas
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Eucreas before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Eucreas.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Eucreas. It is especially important to mention the following:
* glucocorticoids generally used to treat inflammation
* beta-2 agonists generally used to treat respiratory disorders
* other medicines used to treat diabetes
* medicines which increase urine production (diuretics)
* medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
* certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
* certain medicines affecting the thyroid
* certain medicines affecting the nervous system
* certain medicines used to treat angina (e.g. ranolazine)
* certain medicines used to treat HIV infection (e.g. dolutegravir)
* certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (e.g. vandetanib)
* certain medicines used to treat heartburn and peptic ulcers (e.g cimetidine)

Eucreas with alcohol
Avoid excessive alcohol intake while taking Eucreas since this may increase the risk of lactic acidosis (please see section “Warnings and precautions”).

Pregnancy and breast-feeding
* If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risk of taking Eucreas during pregnancy.
* Do not use Eucreas if you are pregnant or breast-feeding (see also “Do not take Eucreas”).

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
If you feel dizzy while taking Eucreas, do not drive or use any tools or machines.

Eucreas® 50 mg/1000 mg film-coated tablets

(vildagliptin/metformin hydrochloride)

Patient Information Leaflet (continued)

3 How to take Eucreas

The amount of Eucreas that people have to take varies depending on their condition. Your doctor will tell you exactly the dose of Eucreas to take.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one film-coated tablet of either 50 mg/850 mg or 50 mg/1000 mg taken twice a day

If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.

Your doctor may prescribe this medicine alone or with certain other medicines that lower the level of sugar in your blood.

When and how to take Eucreas
* Swallow the tablets whole with a glass of water,
* Take one tablet in the morning and the other in the evening with or just after food. Taking the tablet just after food will lower the risk of an upset stomach.

Continue to follow any advice about diet that your doctor has given you. In particular, if you are following a diabetic weight control diet, continue with this while you are taking Eucreas.

If you take more Eucreas than you should
If you take too many Eucreas tablets, or if someone else takes your tablets, **talk to a doctor or pharmacist immediately**. Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take Eucreas
If you forget to take a tablet, take it with your next meal unless you are due to take one then anyway. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Eucreas
Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking Eucreas unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should **stop taking Eucreas and see your doctor immediately** if you experience the following side effects:
* **Lactic acidosis** (very rare: may affect up to 1 in 10 000 people): Eucreas may cause a very rare, but very serious side effect called lactic acidosis (see section “Warnings and precautions”). If this happens you must **stop taking Eucreas and contact a doctor or the nearest hospital immediately,** as lactic acidosis may lead to coma.
* Angioedema (rare: may affect up to 1 in 1 000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives, which may indicate a reaction called “angioedema”.
* Liver disease (hepatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).
* Inflammation of the pancreas (pancreatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects
Some patients have experienced the following side effects while taking Eucreas:
* Common (may affect up to 1 in 10 people): sore throat, runny nose, fever, itchy rash, excessive sweating, joint pain, dizziness, headache, trembling that cannot be controlled, constipation, nausea (feeling sick), vomiting, diarrhoea, flatulence, heartburn, pain in and around the stomach (abdominal pain).
* Uncommon (may affect up to 1 in 100 people): tiredness,weakness, metallic taste, low blood glucose, loss of appetite, swollen hands, ankles or feet (oedema), chills, inflammation of the pancreas, muscle pain.
* Very rare (may affect up to 1 in 10 000 people): signs of a high level of lactic acid in the blood (known as lactic acidosis) such as drowsiness or dizziness, severe nausea or vomiting, abdominal pain, irregular heart beat or deep, rapid breathing; redness of the skin, itching; decreased vitamin B12 levels (paleness, tiredness, mental symptoms such as confusion or memory disturbances).

Since this product has been marketed, the following side effects have also been reported:
* Frequency not known (cannot be estimated from the available data): localised peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin’s surface or bruising.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Eucreas

Do not store above 30°C.
Store in the original package (blister) in order to protect from moisture.
Keep out of the sight and reach of children.
Do not use Eucreas after the expiry date which is stated on the blister or carton label. The expiry date refers to the last day of the month.
If your doctor tells you to stop using this medicine, return any unused tablets to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Eucreas contains:
Each tablet contains 50 mg vildagliptin and 1000 mg metformin hydrochloride.
The other ingredients are hydroxypropylcellulose, magnesium stearate, hypromellose 2910 3cP, titanium dioxide (E171), yellow iron oxide (E172), macrogol 4000 and talc.

What Eucreas looks like and contents of the pack
Dark yellow, ovaloid film-coated tablet with bevelled edge, imprinted with “NVR” on one side and “FLO” on the other side.

Eucreas is available in packs containing 60 film-coated tablets.

Manufacturer and Licence Holder
Manufactured by Lek d.d PE PROIZVODNJA LENDAVA, Trimlini 2D, 9220 Lendava, Slovenia and is procured from within the EU and is repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

For any information about this medicine, please contact the Product Licence Holder, Lexon UK Limited,Tel: 01527 505414.

POM PL 15184/2416 Eucreas 50 mg/1000 mg film-coated tablets

Eucreas is a registered trademark of Novartis AG.

Revision date: 07/05/2026

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Eucreas® 50 mg/1000 mg film-coated tablets

(vildagliptin/metformin hydrochloride)

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Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals. Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

How Eucreas works
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2 What you need to know before you take Eucreas

Do not take Eucreas
* if you are allergic to vildagliptin, metformin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to any of these, talk to your doctor before taking Eucreas.
* if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see “Risk of lactic acidosis” below) or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
* if you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing which could be a sign of heart problems.
* if you have severely reduced kidney function.
* if you have a severe infection or are seriously dehydrated (have lost a lot of water from your body).
* if you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye). Please also see information about this in section “Warnings and precautions”.
* if you have liver problems.
* if you drink alcohol excessively (whether every day or only from time to time).
* if you are breast-feeding (see also “Pregnancy and breast-feeding”).

Warnings and precautions
<u>Risk of lactic acidosis</u>
Eucreas may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Eucreas for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Eucreas and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include:
* vomiting
* stomach ache (abdominal pain)
* muscle cramps
* a general feeling of not being well with severe tiredness
* difficulty in breathing
* reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor promptly for further instructions if:
* You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
* You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

Eucreas is not a substitute for insulin. Therefore, you should not receive Eucreas for the treatment of type 1 diabetes.

Talk to your doctor, pharmacist or nurse before taking Eucreas if you have or have had a disease of the pancreas.

Talk to your doctor, pharmacist or nurse before taking Eucreas if you are taking an anti-diabetic medicine known as a sulphonylurea. Your doctor may want to reduce your dose of the sulphonylurea when you take it together with Eucreas in order to avoid low blood glucose (hypoglycaemia).

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Eucreas. Should these occur, you should promptly consult your doctor.

If you need to have major surgery you must stop taking Eucreas during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Eucreas.

A test to determine your liver function will be performed before the start of Eucreas treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

During treatment with Eucreas, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or have worsening renal function.

Your doctor will test your blood and urine for sugar regularly.

Children and adolescents
The use of Eucreas in children and adolescents up to 18 years of age is not recommended.

Other medicines and Eucreas
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Eucreas before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Eucreas.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Eucreas. It is especially important to mention the following:
* glucocorticoids generally used to treat inflammation
* beta-2 agonists generally used to treat respiratory disorders
* other medicines used to treat diabetes
* medicines which increase urine production (diuretics)
* medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
* certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
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* certain medicines used to treat HIV infection (e.g. dolutegravir)
* certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (e.g. vandetanib)
* certain medicines used to treat heartburn and peptic ulcers (e.g cimetidine)

Eucreas with alcohol
Avoid excessive alcohol intake while taking Eucreas since this may increase the risk of lactic acidosis (please see section “Warnings and precautions”).

Pregnancy and breast-feeding
* If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risk of taking Eucreas during pregnancy.
* Do not use Eucreas if you are pregnant or breast-feeding (see also “Do not take Eucreas”).

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
If you feel dizzy while taking Eucreas, do not drive or use any tools or machines.

Eucreas® 50 mg/1000 mg film-coated tablets

(vildagliptin/metformin hydrochloride)

Patient Information Leaflet (continued)

3 How to take Eucreas

The amount of Eucreas that people have to take varies depending on their condition. Your doctor will tell you exactly the dose of Eucreas to take.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one film-coated tablet of either 50 mg/850 mg or 50 mg/1000 mg taken twice a day

If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.

Your doctor may prescribe this medicine alone or with certain other medicines that lower the level of sugar in your blood.

When and how to take Eucreas
* Swallow the tablets whole with a glass of water,
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Continue to follow any advice about diet that your doctor has given you. In particular, if you are following a diabetic weight control diet, continue with this while you are taking Eucreas.

If you take more Eucreas than you should
If you take too many Eucreas tablets, or if someone else takes your tablets, **talk to a doctor or pharmacist immediately**. Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take Eucreas
If you forget to take a tablet, take it with your next meal unless you are due to take one then anyway. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Eucreas
Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking Eucreas unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

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You should **stop taking Eucreas and see your doctor immediately** if you experience the following side effects:
* **Lactic acidosis** (very rare: may affect up to 1 in 10 000 people): Eucreas may cause a very rare, but very serious side effect called lactic acidosis (see section “Warnings and precautions”). If this happens you must **stop taking Eucreas and contact a doctor or the nearest hospital immediately,** as lactic acidosis may lead to coma.
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* Inflammation of the pancreas (pancreatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects
Some patients have experienced the following side effects while taking Eucreas:
* Common (may affect up to 1 in 10 people): sore throat, runny nose, fever, itchy rash, excessive sweating, joint pain, dizziness, headache, trembling that cannot be controlled, constipation, nausea (feeling sick), vomiting, diarrhoea, flatulence, heartburn, pain in and around the stomach (abdominal pain).
* Uncommon (may affect up to 1 in 100 people): tiredness,weakness, metallic taste, low blood glucose, loss of appetite, swollen hands, ankles or feet (oedema), chills, inflammation of the pancreas, muscle pain.
* Very rare (may affect up to 1 in 10 000 people): signs of a high level of lactic acid in the blood (known as lactic acidosis) such as drowsiness or dizziness, severe nausea or vomiting, abdominal pain, irregular heart beat or deep, rapid breathing; redness of the skin, itching; decreased vitamin B12 levels (paleness, tiredness, mental symptoms such as confusion or memory disturbances).

Since this product has been marketed, the following side effects have also been reported:
* Frequency not known (cannot be estimated from the available data): localised peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin’s surface or bruising.

Reporting of side effects
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5 How to store Eucreas

Do not store above 30°C.
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Keep out of the sight and reach of children.
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Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

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What Eucreas contains:
Each tablet contains 50 mg vildagliptin and 1000 mg metformin hydrochloride.
The other ingredients are hydroxypropylcellulose, magnesium stearate, hypromellose 2910 3cP, titanium dioxide (E171), yellow iron oxide (E172), macrogol 4000 and talc.

What Eucreas looks like and contents of the pack
Dark yellow, ovaloid film-coated tablet with bevelled edge, imprinted with “NVR” on one side and “FLO” on the other side.

Eucreas is available in packs containing 60 film-coated tablets.

Manufacturer and Licence Holder
Manufactured by Novartis Pharmaceutical Manufacturing LLC, Verovškova ulica 57, 1000 Ljubljana, Slovenia and is procured from within the EU and is repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

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For any information about this medicine, please contact the Product Licence Holder, Lexon UK Limited,Tel: 01527 505414.

POM	PL 15184/2416	Eucreas 50 mg/1000 mg film-coated tablets

Eucreas is a registered trademark of Novartis AG.

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Vildagliptin/Metformin hydrochloride 50mg/1000mg film-coated tablets

Patient Information Leaflet

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* This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
* If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Vildagliptin/Metformin hydrochloride 50mg/1000mg film-coated tablets but will be referred to as Vildagliptin and Metformin throughout the leaflet. Please note that the leaflet also contains information about another strength of this medicine, Vildagliptin/Metformin hydrochloride 50mg/850mg film-coated tablets.

What is in this leaflet

1 What Vildagliptin and Metformin is and what it is used for

The active substances of Vildagliptin and Metformin, vildagliptin and metformin, belong to a group of medicines called “oral antidiabetics”.

Vildagliptin and Metformin is used to treat adult patients with type 2 diabetes. This type of diabetes is also known as non-insulin-dependent diabetes mellitus. Vildagliptin and Metformin is used when diabetes cannot be controlled by diet and exercise alone and/or with other medicines used to treat diabetes (insulin or sulphonylureas).

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals. Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

How Vildagliptin and Metformin works
Both active substances, vildagliptin and metformin, help to control the level of sugar in the blood. The substance vildagliptin works by making the pancreas produce more insulin and less glucagon. The substance metformin works by helping the body to make better use of insulin. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes.

2 What you need to know before you take Vildagliptin and Metformin

Do not take Vildagliptin and Metformin
* if you are allergic to vildagliptin, metformin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to any of these, talk to your doctor before taking Vildagliptin and Metformin.
* if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see “Risk of lactic acidosis” below) or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
* if you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing which could be a sign of heart problems.
* if you have severely reduced kidney function.
* if you have a severe infection or are seriously dehydrated (have lost a lot of water from your body).
* if you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye). Please also see information about this in section “Warnings and precautions”.
* if you have liver problems.
* if you drink alcohol excessively (whether every day or only from time to time).
* if you are breast-feeding (see also “Pregnancy and breast-feeding”).

Warnings and precautions
<u>Risk of lactic acidosis</u>
Vildagliptin and Metformin may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Vildagliptin and Metformin for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Vildagliptin and Metformin and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include:
* vomiting
* stomach ache (abdominal pain)
* muscle cramps
* a general feeling of not being well with severe tiredness
* difficulty in breathing
* reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor promptly for further instructions if:
* You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
* You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

Vildagliptin and Metformin is not a substitute for insulin. Therefore, you should not receive Vildaglipton and Metformin for the treatment of type 1 diabetes.

Talk to your doctor, pharmacist or nurse before taking Vildagliptin and Metformin if you have or have had a disease of the pancreas.

Talk to your doctor, pharmacist or nurse before taking Vildagliptin and Metformin if you are taking an anti-diabetic medicine known as a sulphonylurea. Your doctor may want to reduce your dose of the sulphonylurea when you take it together with Vildagliptin and Metformin in order to avoid low blood glucose (hypoglycaemia).

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Vildagliptin and Metformin. Should these occur, you should promptly consult your doctor.

If you need to have major surgery you must stop taking Vildagliptin and Metformin during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Vildagliptin and Metformin .

A test to determine your liver function will be performed before the start of Vildagliptin and Metformin treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

During treatment with Vildagliptin and Metformin, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or have worsening renal function.

Your doctor will test your blood and urine for sugar regularly.

Children and adolescents
The use of Vildagliptin and Metformin in children and adolescents up to 18 years of age is not recommended.

Other medicines and Vildagliptin and Metformin
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Vildagliptin and Metformin before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Vildagliptin and Metformin.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Vildagliptin and Metformin. It is especially important to mention the following:
* glucocorticoids generally used to treat inflammation
* beta-2 agonists generally used to treat respiratory disorders
* other medicines used to treat diabetes
* medicines which increase urine production (diuretics)
* medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
* certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
* certain medicines affecting the thyroid
* certain medicines affecting the nervous system
* certain medicines used to treat angina (e.g. ranolazine)
* certain medicines used to treat HIV infection (e.g. dolutegravir)
* certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (e.g. vandetanib)
* certain medicines used to treat heartburn and peptic ulcers (e.g cimetidine)

Vildagliptin and Metformin with alcohol
Avoid excessive alcohol intake while taking Vildagliptin and Metformin since this may increase the risk of lactic acidosis (please see section “Warnings and precautions”).

Vildagliptin/Metformin hydrochloride 50mg/1000mg film-coated tablets

Patient Information Leaflet (continued)

Pregnancy and breast-feeding
* If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risk of taking Vildagliptin and Metformin during pregnancy.
* Do not use Vildagliptin and Metformin if you are pregnant or breast-feeding (see also "Do not take Vildagliptin and Metformin").

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
If you feel dizzy while taking Vildagliptin and Metformin, do not drive or use any tools or machines.

3 How to take Vildagliptin and Metformin

The amount of Vildagliptin and Metformin that people have to take varies depending on their condition. Your doctor will tell you exactly the dose of Vildagliptin and Metformin to take.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one film-coated tablet of either 50 mg/850 mg or 50 mg/1000 mg taken twice a day

If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.

Your doctor may prescribe this medicine alone or with certain other medicines that lower the level of sugar in your blood.

When and how to take Vildagliptin and Metformin
* Swallow the tablets whole with a glass of water,
* Take one tablet in the morning and the other in the evening with or just after food. Taking the tablet just after food will lower the risk of an upset stomach.

Continue to follow any advice about diet that your doctor has given you. In particular, if you are following a diabetic weight control diet, continue with this while you are taking Vildagliptin and Metformin.

If you take more Vildagliptin and Metformin than you should
If you take too many Vildagliptin and Metformin tablets, or if someone else takes your tablets, **talk to a doctor or pharmacist immediately**. Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take Vildagliptin and Metformin
If you forget to take a tablet, take it with your next meal unless you are due to take one then anyway. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Vildagliptin and Metformin
Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking Vildagliptin and Metformin unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should **stop taking Vildagliptin and Metformin and see your doctor immediately** if you experience the following side effects:
* **Lactic acidosis** (very rare: may affect up to 1 in 10 000 people): Vildagliptin and Metformin may cause a very rare, but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens you must **stop taking Vildagliptin and Metformin and contact a doctor or the nearest hospital immediately,** as lactic acidosis may lead to coma.
* Angioedema (rare: may affect up to 1 in 1 000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives, which may indicate a reaction called "angioedema".
* Liver disease (hepatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).
* Inflammation of the pancreas (pancreatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects
Some patients have experienced the following side effects while taking Vildagliptin and Metformin:
* Common (may affect up to 1 in 10 people): sore throat, runny nose, fever, itchy rash, excessive sweating, joint pain, dizziness, headache, trembling that cannot be controlled, constipation, nausea (feeling sick), vomiting, diarrhoea, flatulence, heartburn, pain in and around the stomach (abdominal pain).
* Uncommon (may affect up to 1 in 100 people): tiredness,weakness, metallic taste, low blood glucose, loss of appetite, swollen hands, ankles or feet (oedema), chills, inflammation of the pancreas, muscle pain.
* Very rare (may affect up to 1 in 10 000 people): signs of a high level of lactic acid in the blood (known as lactic acidosis) such as drowsiness or dizziness, severe nausea or vomiting, abdominal pain, irregular heart beat or deep, rapid breathing; redness of the skin, itching; decreased vitamin B12 levels (paleness, tiredness, mental symptoms such as confusion or memory disturbances).

Since this product has been marketed, the following side effects have also been reported:
* Frequency not known (cannot be estimated from the available data): localised peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Vildagliptin and Metformin

Do not store above 30°C.
Store in the original package (blister) in order to protect from moisture.
Keep out of the sight and reach of children.
Do not use Vildagliptin and Metformin after the expiry date which is stated on the blister or carton label. The expiry date refers to the last day of the month.
If your doctor tells you to stop using this medicine, return any unused tablets to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Vildagliptin and Metformin contains:
Each tablet contains 50 mg vildagliptin and 1000 mg metformin hydrochloride.
The other ingredients are hydroxypropylcellulose, magnesium stearate, hypromellose 2910 3cP, titanium dioxide (E171), yellow iron oxide (E172), macrogol 4000 and talc.

What Vildagliptin and Metformin looks like and contents of the pack
Dark yellow, ovaloid film-coated tablet with bevelled edge, imprinted with "NVR" on one side and "FLO" on the other side.

Vildagliptin/Metformin hydrochloride is available in packs containing 60 film-coated tablets.

Manufacturer and Licence Holder
Manufactured by Lek d.d PE PROIZVODNJA LENDAVA, Trimlini 2D, 9220 Lendava, Slovenia and is procured from within the EU and is repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

For any information about this medicine, please contact the Product Licence Holder, Lexon UK Limited,Tel: 01527 505414.

POM PL 15184/2416 Vildagliptin/Metformin hydrochloride 50mg/1000mg film-coated tablets

Revision date: 07/05/2026

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you

Vildagliptin/Metformin hydrochloride 50mg/1000mg film-coated tablets

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
* Keep this leaflet. You may need to read it again.
* If you have any further questions, ask your doctor, pharmacist or nurse.
* This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
* If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Vildagliptin/Metformin hydrochloride 50mg/1000mg film-coated tablets but will be referred to as Vildagliptin and Metformin throughout the leaflet. Please note that the leaflet also contains information about another strength of this medicine, Vildagliptin/Metformin hydrochloride 50mg/850mg film-coated tablets.

What is in this leaflet

1 What Vildagliptin and Metformin is and what it is used for

The active substances of Vildagliptin and Metformin, vildagliptin and metformin, belong to a group of medicines called “oral antidiabetics”.

Vildagliptin and Metformin is used to treat adult patients with type 2 diabetes. This type of diabetes is also known as non-insulin-dependent diabetes mellitus. Vildagliptin and Metformin is used when diabetes cannot be controlled by diet and exercise alone and/or with other medicines used to treat diabetes (insulin or sulphonylureas).

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals. Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

How Vildagliptin and Metformin works
Both active substances, vildagliptin and metformin, help to control the level of sugar in the blood. The substance vildagliptin works by making the pancreas produce more insulin and less glucagon. The substance metformin works by helping the body to make better use of insulin. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes.

2 What you need to know before you take Vildagliptin and Metformin

Do not take Vildagliptin and Metformin
* if you are allergic to vildagliptin, metformin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to any of these, talk to your doctor before taking Vildagliptin and Metformin.
* if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see “Risk of lactic acidosis” below) or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
* if you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing which could be a sign of heart problems.
* if you have severely reduced kidney function.
* if you have a severe infection or are seriously dehydrated (have lost a lot of water from your body).
* if you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye). Please also see information about this in section “Warnings and precautions”.
* if you have liver problems.
* if you drink alcohol excessively (whether every day or only from time to time).
* if you are breast-feeding (see also “Pregnancy and breast-feeding”).

Warnings and precautions
<u>Risk of lactic acidosis</u>
Vildagliptin and Metformin may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Vildagliptin and Metformin for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Vildagliptin and Metformin and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include:
* vomiting
* stomach ache (abdominal pain)
* muscle cramps
* a general feeling of not being well with severe tiredness
* difficulty in breathing
* reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor promptly for further instructions if:
* You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
* You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

Vildagliptin and Metformin is not a substitute for insulin. Therefore, you should not receive Vildaglipton and Metformin for the treatment of type 1 diabetes.

Talk to your doctor, pharmacist or nurse before taking Vildagliptin and Metformin if you have or have had a disease of the pancreas.

Talk to your doctor, pharmacist or nurse before taking Vildagliptin and Metformin if you are taking an anti-diabetic medicine known as a sulphonylurea. Your doctor may want to reduce your dose of the sulphonylurea when you take it together with Vildagliptin and Metformin in order to avoid low blood glucose (hypoglycaemia).

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Vildagliptin and Metformin. Should these occur, you should promptly consult your doctor.

If you need to have major surgery you must stop taking Vildagliptin and Metformin during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Vildagliptin and Metformin .

A test to determine your liver function will be performed before the start of Vildagliptin and Metformin treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

During treatment with Vildagliptin and Metformin, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or have worsening renal function.

Your doctor will test your blood and urine for sugar regularly.

Children and adolescents
The use of Vildagliptin and Metformin in children and adolescents up to 18 years of age is not recommended.

Other medicines and Vildagliptin and Metformin
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Vildagliptin and Metformin before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Vildagliptin and Metformin.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Vildagliptin and Metformin. It is especially important to mention the following:
* glucocorticoids generally used to treat inflammation
* beta-2 agonists generally used to treat respiratory disorders
* other medicines used to treat diabetes
* medicines which increase urine production (diuretics)
* medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
* certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
* certain medicines affecting the thyroid
* certain medicines affecting the nervous system
* certain medicines used to treat angina (e.g. ranolazine)
* certain medicines used to treat HIV infection (e.g. dolutegravir)
* certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (e.g. vandetanib)
* certain medicines used to treat heartburn and peptic ulcers (e.g cimetidine)

Vildagliptin and Metformin with alcohol
Avoid excessive alcohol intake while taking Vildagliptin and Metformin since this may increase the risk of lactic acidosis (please see section “Warnings and precautions”).

Vildagliptin/Metformin hydrochloride 50mg/1000mg film-coated tablets

Patient Information Leaflet (continued)

Pregnancy and breast-feeding
* If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risk of taking Vildagliptin and Metformin during pregnancy.
* Do not use Vildagliptin and Metformin if you are pregnant or breast-feeding (see also "Do not take Vildagliptin and Metformin").

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
If you feel dizzy while taking Vildagliptin and Metformin, do not drive or use any tools or machines.

3 How to take Vildagliptin and Metformin

The amount of Vildagliptin and Metformin that people have to take varies depending on their condition. Your doctor will tell you exactly the dose of Vildagliptin and Metformin to take.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one film-coated tablet of either 50 mg/850 mg or 50 mg/1000 mg taken twice a day

If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.

Your doctor may prescribe this medicine alone or with certain other medicines that lower the level of sugar in your blood.

When and how to take Vildagliptin and Metformin
* Swallow the tablets whole with a glass of water,
* Take one tablet in the morning and the other in the evening with or just after food. Taking the tablet just after food will lower the risk of an upset stomach.

Continue to follow any advice about diet that your doctor has given you. In particular, if you are following a diabetic weight control diet, continue with this while you are taking Vildagliptin and Metformin.

If you take more Vildagliptin and Metformin than you should
If you take too many Vildagliptin and Metformin tablets, or if someone else takes your tablets, **talk to a doctor or pharmacist immediately**. Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take Vildagliptin and Metformin
If you forget to take a tablet, take it with your next meal unless you are due to take one then anyway. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Vildagliptin and Metformin
Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking Vildagliptin and Metformin unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should **stop taking Vildagliptin and Metformin and see your doctor immediately** if you experience the following side effects:
* **Lactic acidosis** (very rare: may affect up to 1 in 10 000 people): Vildagliptin and Metformin may cause a very rare, but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens you must **stop taking Vildagliptin and Metformin and contact a doctor or the nearest hospital immediately,** as lactic acidosis may lead to coma.
* Angioedema (rare: may affect up to 1 in 1 000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives, which may indicate a reaction called "angioedema".
* Liver disease (hepatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).
* Inflammation of the pancreas (pancreatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects
Some patients have experienced the following side effects while taking Vildagliptin and Metformin:
* Common (may affect up to 1 in 10 people): sore throat, runny nose, fever, itchy rash, excessive sweating, joint pain, dizziness, headache, trembling that cannot be controlled, constipation, nausea (feeling sick), vomiting, diarrhoea, flatulence, heartburn, pain in and around the stomach (abdominal pain).
* Uncommon (may affect up to 1 in 100 people): tiredness,weakness, metallic taste, low blood glucose, loss of appetite, swollen hands, ankles or feet (oedema), chills, inflammation of the pancreas, muscle pain.
* Very rare (may affect up to 1 in 10 000 people): signs of a high level of lactic acid in the blood (known as lactic acidosis) such as drowsiness or dizziness, severe nausea or vomiting, abdominal pain, irregular heart beat or deep, rapid breathing; redness of the skin, itching; decreased vitamin B12 levels (paleness, tiredness, mental symptoms such as confusion or memory disturbances).

Since this product has been marketed, the following side effects have also been reported:
* Frequency not known (cannot be estimated from the available data): localised peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Vildagliptin and Metformin

Do not store above 30°C.
Store in the original package (blister) in order to protect from moisture.
Keep out of the sight and reach of children.
Do not use Vildagliptin and Metformin after the expiry date which is stated on the blister or carton label. The expiry date refers to the last day of the month.
If your doctor tells you to stop using this medicine, return any unused tablets to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Vildagliptin and Metformin contains:
Each tablet contains 50 mg vildagliptin and 1000 mg metformin hydrochloride.
The other ingredients are hydroxypropylcellulose, magnesium stearate, hypromellose 2910 3cP, titanium dioxide (E171), yellow iron oxide (E172), macrogol 4000 and talc.

What Vildagliptin and Metformin looks like and contents of the pack
Dark yellow, ovaloid film-coated tablet with bevelled edge, imprinted with "NVR" on one side and "FLO" on the other side.

Vildagliptin/Metformin hydrochloride is available in packs containing 60 film-coated tablets.

Manufacturer and Licence Holder
Manufactured by Novartis Pharmaceutical Manufacturing LLC, Verovškova ulica 57, 1000 Ljubljana, Slovenia and is procured from within the EU and is repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

For any information about this medicine, please contact the Product Licence Holder, Lexon UK Limited,Tel: 01527 505414.

POM PL 15184/2416 Vildagliptin/Metformin hydrochloride 50mg/1000mg film-coated tablets

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