Package leaflet: Information for the patient

Xigduo® 5 mg/1,000 mg film-coated tablets

(dapagliflozin/metformin hydrochloride)

This medicine is called Xigduo 5 mg/1,000 mg film-coated tablets, but will be referred to as Xigduo throughout this leaflet. Another strength is available.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xigduo is and what it is used for
2. What you need to know before you take Xigduo
3. How to take Xigduo
4. Possible side effects
5. How to store Xigduo
6. Contents of the pack and other information

1. What Xigduo is and what it is used for

This medicine contains two different substances called dapagliflozin and metformin. Both belong to a group of medicines called oral anti-diabetics. These are medicines taken by mouth for diabetes.
Xigduo is used for a type of diabetes called “type 2 diabetes” in adult patients (aged 18 years and older) and usually occurs when you are older. If you have type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use the insulin it produces properly. This leads to a high level of sugar (glucose) in your blood.
- Dapagliflozin works by removing excess sugar from your body via your urine and lowers the amount of sugar in your blood. It can also help prevent heart disease.
- Metformin works mainly by inhibiting glucose production in the liver.

To treat diabetes:
- This medicine is taken in combination with diet and exercise.
- This medicine is used if your diabetes cannot be controlled with other medicines used to treat diabetes.
- Your doctor may ask you to take this medicine on its own or together with other medicines to treat diabetes. This may be another medicine taken by mouth and/or a medicine given by injection, such as insulin or a GLP-1 receptor agonist (helps your body to increase the production of insulin when your blood sugar is high).
- If you are already taking both dapagliflozin and metformin as single tablets, your doctor may ask you to switch to this medicine. To avoid overdose, do not continue taking dapagliflozin and metformin tablets, if you are taking Xigduo.

It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

2. What you need to know before you take Xigduo

Do not take Xigduo
- if you are allergic to dapagliflozin, metformin or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had a diabetic coma.
- 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 a diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- if you have severely reduced kidney function.
- if you have a severe infection.
- if you have lost a lot of water from your body (dehydration), e.g. due to long-lasting or severe diarrhoea, or if you have vomited several times in a row.
- 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.
- if you have problems with your liver.
- if you drink large amounts of alcohol, either every day or only from time to time (please see section “Xigduo with alcohol”).

Do not take this medicine if any of the above apply to you.

Warnings and precautions

<u>Risk of lactic acidosis</u>
Xigduo 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 Xigduo 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 Xigduo 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 Encephalomyopathy with Lactic acidosis, and Stroke-like episodes) or Maternally Inherited Diabetes and Deafness (MIDD).
- if 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.

Talk to your doctor, pharmacist or nurse before taking Xigduo, and during treatment:
- if you have “type 1 diabetes” – the type that usually starts when you are young, and your body does not produce any insulin. Xigduo should not be used to treat this condition.
- if you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, contact a doctor or the nearest hospital straight away. These symptoms could be a sign of “diabetic ketoacidosis” – a rare but serious, sometimes life-threatening problem you can get with diabetes because of increased levels of “ketone bodies” in your urine or blood, seen in tests. The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.
- if you have problems with your kidneys. Your doctor will check your kidney function.
- if you have very high levels of glucose in your blood which may make you dehydrated (lose too much body fluid). Possible signs of dehydration are listed at the top of section 4. Tell your doctor before you start taking this medicine if you have any of these signs.
- if you are taking medicines to lower blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). More information is given below under ‘Other medicines and Xigduo’.
- if you often get infections of the urinary tract. This medicine may cause urinary tract infections and your doctor may want to monitor you more closely. Your doctor may consider temporarily changing your treatment if you develop a serious infection.

If you need to have major surgery, you must stop taking Xigduo during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Xigduo.
It is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.
If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking this medicine.
Talk to your doctor immediately if you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier’s gangrene which destroys the tissue under the skin. Fournier’s gangrene has to be treated immediately.

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

Urine glucose
Because of how this medicine works, your urine will test positive for sugar while you are on this medicine.

Children and adolescents
This medicine is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

Other medicines and Xigduo
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 Xigduo before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Xigduo.
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 adjust the dosage of Xigduo.
It is especially important to mention the following:
- if you are taking medicines which increase urine production (diuretics). Your doctor may ask you to stop taking this medicine. Possible signs of losing too much fluid from your body are listed at the top of section 4.
- if you are taking other medicines that lower the amount of sugar in your blood such as insulin or a “sulphonylurea” medicine. Your doctor may want to lower the dose of these other medicines, to prevent you from getting blood sugar levels that are too low (hypoglycaemia).
- if you are taking cimetidine, a medicine used to treat stomach problems.
- if you are using bronchodilators (beta-2 agonists) which are used to treat asthma.
- if you are using corticosteroids (used to treat inflammation in diseases like asthma and arthritis) that are given by mouth, as an injection, or inhaled.
- if you are using medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- if you are using certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should stop taking this medicine if you become pregnant, since it is not recommended during the second and third trimesters (the last six months) of pregnancy. Talk to your doctor about the best way to control your blood sugar while you are pregnant.
Talk to your doctor if you would like to or are breast-feeding before taking this medicine. You should not use this medicine if you are breast-feeding. Metformin passes into human milk in small amounts. It is not known if dapagliflozin passes into human breast milk.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines. Taking it with other medicines that lower the amount of sugar in your blood, such as insulin or a “sulphonylurea” medicine, can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as weakness, dizziness, increased sweating, fast heart beat, change in vision or difficulties concentrating, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you start to feel these symptoms.

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially ‘sodium-free’.

3. How to take Xigduo

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

How much to take
- The amount of this medicine that you will take varies depending on your condition and the doses you currently take of metformin and/or individual tablets of dapagliflozin and metformin. Your doctor will tell you exactly which strength of this medicine to take.
- The recommended dose is one tablet twice a day.

Taking this medicine
- Swallow the tablet whole with half a glass of water.
- Take your tablet with food. This is to reduce the risk of side effects in the stomach.
- Take your tablet twice daily, once in the morning (breakfast) and once in the evening (dinner).

Your doctor may prescribe this medicine together with other medicine(s) to lower the amount of sugar in your blood. These may be medicine(s) by mouth or given by injection, such as insulin or a GLP-1 receptor agonist.
Remember to take these other medicine(s) as your doctor has told you. This will help get the best results for your health.

Diet and exercise
To control your diabetes, you still need to keep to diet and exercise, even when you are taking this medicine. So it is important to keep following the advice about diet and exercise from your doctor, pharmacist or nurse. In particular, if you are following a diabetic weight control diet, continue to follow it while you are taking this medicine.

If you take more Xigduo than you should
If you take more Xigduo tablets than you should, you may experience lactic acidosis. Symptoms of lactic acidosis include feeling or being very sick, vomiting, stomach ache, muscular cramps, severe tiredness or difficulty breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking this medicine immediately and contact a doctor or the nearest hospital straight away (see section 2). Take the medicine pack with you.

If you forget to take Xigduo
If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule.
Do not take a double dose of this medicine to make up for a forgotten dose.

If you stop taking Xigduo
Do not stop taking this medicine without talking to your doctor first. Your blood sugar may increase without this medicine.
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.

Stop taking Xigduo and see a doctor straight away if you notice any of the following serious or potentially serious side effects:
- **Lactic acidosis**, seen very rarely (may affect up to 1 in 10,000 people)

Xigduo 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 Xigduo and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Contact a doctor or the nearest hospital straight away if you have any of the following side effects:
- **Diabetic ketoacidosis**, seen rarely (may affect up to 1 in 1,000 people)

These are the signs of diabetic ketoacidosis (see also section 2 Warnings and precautions):
- increased levels of “ketone bodies” in your urine or blood
- rapid weight loss
- feeling sick or being sick
- stomach pain
- excessive thirst
- fast and deep breathing
- confusion
- unusual sleepiness or tiredness
- a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat.

This may occur regardless of blood glucose level. Your doctor may decide to temporarily or permanently stop your treatment with Xigduo.
- **Necrotising fasciitis of the perineum** or Fournier’s gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus, seen very rarely.

Stop taking Xigduo and see a doctor as soon as possible if you notice any of the following serious or potentially serious effects:
- **Dehydration: loss of too much fluid from your body**, seen uncommonly (may affect up to 1 in 100 people).

These are signs of dehydration:
- very dry or sticky mouth, feeling very thirsty
- feeling very sleepy or tired
- passing little or no water (urine)
- fast heartbeat.
- **Urinary tract infection**, seen commonly (may affect up to 1 in 10 people).

These are signs of a severe infection of the urinary tract:
- fever and/or chills
- burning sensation when passing water (urinating)
- pain in your back or side.

Although uncommon, if you see blood in your urine, tell your doctor immediately.

Contact your doctor as soon as possible if you have any of the following side effects:
- **Low blood sugar levels (hypoglycaemia)**, seen very commonly (may affect more than 1 in 10 people) - when taking this medicine with a sulphonylurea or other medicines that lower the amount of sugar in your blood, such as insulin.

These are the signs of low blood sugar:
- shaking, sweating, feeling very anxious, fast heart beat
- feeling hungry, headache, change in vision
- a change in your mood or feeling confused.

Your doctor will tell you how to treat low blood sugar levels and what to do if you get any of the signs above. If you have symptoms of low blood sugar, eat glucose tablets, a high sugar snack or drink fruit juice. Measure your blood sugar if possible and rest.

Other side effects include:

Very common
- nausea, vomiting
- diarrhoea or stomach ache
- loss of appetite

Common
- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- back pain
- discomfort when passing water (urine), passing more water than usual or needing to pass water more often
- changes in the amount of cholesterol or fats in your blood (shown in tests)
- increases in the amount of red blood cells in your blood (shown in tests)
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment
- changes in taste
- dizziness
- rash
- decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Uncommon
- thirst
- constipation
- awakening from sleep at night to pass urine
- dry mouth
- weight decreased
- increases in creatinine (shown in laboratory blood tests) in the beginning of treatment
- increases in urea (shown in laboratory blood tests)

Very rare
- abnormalities in liver function tests, inflammation of the liver (hepatitis)
- redness of the skin (erythema), itching or an itchy rash (hives)

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 the Yellow Card Scheme, Website: 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 Xigduo

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the blister or carton after ‘EXP’. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xigduo contains
- The active substances are dapagliflozin and metformin hydrochloride (metformin HCl).
  Each Xigduo 5 mg/1,000 mg film-coated tablet (tablet) contains dapagliflozin propanediol monohydrate equivalent to 5 mg dapagliflozin and 1,000 mg metformin hydrochloride.
- The other ingredients are:
  - tablet core: hydroxypropyl cellulose (E463), microcrystalline cellulose (E460(i)), magnesium stearate (E470b), sodium starch glycolate (type A).
  - film-coating: polyvinyl alcohol (E1203), macrogol 3350 (E1521), talc (E553b), titanium dioxide (E171), iron oxide yellow (E172).

What Xigduo looks like and contents of the pack
Xigduo 5 mg/1,000 mg are 10.5 x 21.5 mm oval, yellow film-coated tablets. They have “5/1000” on one side and “1069” on the other side.
Xigduo 5 mg/1,000 mg film-coated tablets are available in packs of 56 film-coated tablets in non-perforated blisters.

Manufacturer
AstraZeneca AB
Gärtunavägen
SE-152 57 Södertälje
Sweden
Procured from within the EU and repackaged on behalf of the Product Licence Holder Mediwin PPIP Ltd., 13 Martello Enterprise Centre, Courtwick Lane, Littlehampton, BN17 7PA, UK.

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This leaflet was last revised on 01/10/2025
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PIL-XIO-UK2442-A

Package leaflet: Information for the patient

Dapagliflozin/Metformin hydrochloride 5 mg/1,000 mg film-coated tablets

This medicine is called Dapagliflozin/Metformin hydrochloride 5 mg/1,000 mg film-coated tablets, but will be referred to as Dapagliflozin/Metformin hydrochloride throughout this leaflet. Another strength is available.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dapagliflozin/Metformin hydrochloride is and what it is used for
2. What you need to know before you take Dapagliflozin/Metformin hydrochloride
3. How to take Dapagliflozin/Metformin hydrochloride
4. Possible side effects
5. How to store Dapagliflozin/Metformin hydrochloride
6. Contents of the pack and other information

1. What Dapagliflozin/Metformin hydrochloride is and what it is used for

This medicine contains two different substances called dapagliflozin and metformin. Both belong to a group of medicines called oral anti-diabetics. These are medicines taken by mouth for diabetes. Dapagliflozin/Metformin hydrochloride is used for a type of diabetes called “type 2 diabetes” in adult patients (aged 18 years and older) and usually occurs when you are older. If you have type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use the insulin it produces properly. This leads to a high level of sugar (glucose) in your blood.
- Dapagliflozin works by removing excess sugar from your body via your urine and lowers the amount of sugar in your blood. It can also help prevent heart disease.
- Metformin works mainly by inhibiting glucose production in the liver.

To treat diabetes:
- This medicine is taken in combination with diet and exercise.
- This medicine is used if your diabetes cannot be controlled with other medicines used to treat diabetes.
- Your doctor may ask you to take this medicine on its own or together with other medicines to treat diabetes. This may be another medicine taken by mouth and/or a medicine given by injection, such as insulin or a GLP-1 receptor agonist (helps your body to increase the production of insulin when your blood sugar is high).
- If you are already taking both dapagliflozin and metformin as single tablets, your doctor may ask you to switch to this medicine. To avoid overdose, do not continue taking dapagliflozin and metformin tablets, if you are taking Dapagliflozin/Metformin hydrochloride.

It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

2. What you need to know before you take Dapagliflozin/Metformin hydrochloride

Do not take Dapagliflozin/Metformin hydrochloride
- if you are allergic to dapagliflozin, metformin or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had a diabetic coma.
- 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 a diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- if you have severely reduced kidney function.
- if you have a severe infection.
- if you have lost a lot of water from your body (dehydration), e.g. due to long-lasting or severe diarrhoea, or if you have vomited several times in a row.
- 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.
- if you have problems with your liver.
- if you drink large amounts of alcohol, either every day or only from time to time (please see section “Dapagliflozin/Metformin hydrochloride with alcohol”).

Do not take this medicine if any of the above apply to you.

Warnings and precautions

Risk of lactic acidosis
Dapagliflozin/Metformin hydrochloride 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 Dapagliflozin/Metformin hydrochloride 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 Dapagliflozin/Metformin hydrochloride 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 Encephalomyopathy with Lactic acidosis, and Stroke-like episodes) or Maternally Inherited Diabetes and Deafness (MIDD).
- if 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.

Talk to your doctor, pharmacist or nurse before taking Dapagliflozin/Metformin hydrochloride, and during treatment:
- if you have “type 1 diabetes” – the type that usually starts when you are young, and your body does not produce any insulin. Dapagliflozin/Metformin hydrochloride should not be used to treat this condition.
- if you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, contact a doctor or the nearest hospital straight away. These symptoms could be a sign of “diabetic ketoacidosis” – a rare but serious, sometimes life-threatening problem you can get with diabetes because of increased levels of “ketone bodies” in your urine or blood, seen in tests. The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.
- if you have problems with your kidneys. Your doctor will check your kidney function.
- if you have very high levels of glucose in your blood which may make you dehydrated (lose too much body fluid). Possible signs of dehydration are listed at the top of section 4. Tell your doctor before you start taking this medicine if you have any of these signs.
- if you are taking medicines to lower blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). More information is given below under ‘Other medicines and Dapagliflozin/Metformin hydrochloride’.
- if you often get infections of the urinary tract. This medicine may cause urinary tract infections and your doctor may want to monitor you more closely. Your doctor may consider temporarily changing your treatment if you develop a serious infection.

If you need to have major surgery, you must stop taking Dapagliflozin/Metformin hydrochloride during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Dapagliflozin/Metformin hydrochloride.
It is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.
If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking this medicine.
Talk to your doctor immediately if you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier’s gangrene which destroys the tissue under the skin. Fournier’s gangrene has to be treated immediately.

Kidney function
During treatment with Dapagliflozin/Metformin hydrochloride, your doctor will check your kidney function at least once every year or more frequently if you are elderly and/or if you have worsening kidney function.

Urine glucose
Because of how this medicine works, your urine will test positive for sugar while you are on this medicine.

Children and adolescents
This medicine is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

Other medicines and Dapagliflozin/Metformin hydrochloride
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 Dapagliflozin/Metformin hydrochloride before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Dapagliflozin/Metformin hydrochloride.
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 adjust the dosage of Dapagliflozin/Metformin hydrochloride. It is especially important to mention the following:
- if you are taking medicines which increase urine production (diuretics). Your doctor may ask you to stop taking this medicine. Possible signs of losing too much fluid from your body are listed at the top of section 4.
- if you are taking other medicines that lower the amount of sugar in your blood such as insulin or a “sulphonylurea” medicine. Your doctor may want to lower the dose of these other medicines, to prevent you from getting blood sugar levels that are too low (hypoglycaemia).
- if you are taking cimetidine, a medicine used to treat stomach problems.
- if you are using bronchodilators (beta-2 agonists) which are used to treat asthma.
- if you are using corticosteroids (used to treat inflammation in diseases like asthma and arthritis) that are given by mouth, as an injection, or inhaled.
- if you are using medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- if you are using certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should stop taking this medicine if you become pregnant, since it is not recommended during the second and third trimesters (the last six months) of pregnancy. Talk to your doctor about the best way to control your blood sugar while you are pregnant.
Talk to your doctor if you would like to or are breast-feeding before taking this medicine. You should not use this medicine if you are breast-feeding. Metformin passes into human milk in small amounts. It is not known if dapagliflozin passes into human breast milk.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines. Taking it with other medicines that lower the amount of sugar in your blood, such as insulin or a “sulphonylurea” medicine, can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as weakness, dizziness, increased sweating, fast heart beat, change in vision or difficulties concentrating, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you start to feel these symptoms.

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially ‘sodium-free’.

3. How to take Dapagliflozin/Metformin hydrochloride

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

How much to take
- The amount of this medicine that you will take varies depending on your condition and the doses you currently take of metformin and/or individual tablets of dapagliflozin and metformin. Your doctor will tell you exactly which strength of this medicine to take.
- The recommended dose is one tablet twice a day.

Taking this medicine
- Swallow the tablet whole with half a glass of water.
- Take your tablet with food. This is to reduce the risk of side effects in the stomach.
- Take your tablet twice daily, once in the morning (breakfast) and once in the evening (dinner).

Your doctor may prescribe this medicine together with other medicine(s) to lower the amount of sugar in your blood. These may be medicine(s) by mouth or given by injection, such as insulin or a GLP-1 receptor agonist.
Remember to take these other medicine(s) as your doctor has told you. This will help get the best results for your health.

Diet and exercise
To control your diabetes, you still need to keep to diet and exercise, even when you are taking this medicine. So it is important to keep following the advice about diet and exercise from your doctor, pharmacist or nurse. In particular, if you are following a diabetic weight control diet, continue to follow it while you are taking this medicine.

If you take more Dapagliflozin/Metformin hydrochloride than you should
If you take more Dapagliflozin/Metformin hydrochloride tablets than you should, you may experience lactic acidosis. Symptoms of lactic acidosis include feeling or being very sick, vomiting, stomach ache, muscular cramps, severe tiredness or difficulty breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking this medicine immediately and contact a doctor or the nearest hospital straight away (see section 2). Take the medicine pack with you.

If you forget to take Dapagliflozin/Metformin hydrochloride
If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule.
Do not take a double dose of this medicine to make up for a forgotten dose.

If you stop taking Dapagliflozin/Metformin hydrochloride
Do not stop taking this medicine without talking to your doctor first. Your blood sugar may increase without this medicine.
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.

Stop taking Dapagliflozin/Metformin hydrochloride and see a doctor straight away if you notice any of the following serious or potentially serious side effects:
- **Lactic acidosis**, seen very rarely (may affect up to 1 in 10,000 people)

Dapagliflozin/Metformin hydrochloride 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 Dapagliflozin/Metformin hydrochloride and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Contact a doctor or the nearest hospital straight away if you have any of the following side effects:
- **Diabetic ketoacidosis**, seen rarely (may affect up to 1 in 1,000 people)

These are the signs of diabetic ketoacidosis (see also section 2 Warnings and precautions):
- increased levels of “ketone bodies” in your urine or blood
- rapid weight loss
- feeling sick or being sick
- stomach pain
- excessive thirst
- fast and deep breathing
- confusion
- unusual sleepiness or tiredness
- a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat.

This may occur regardless of blood glucose level. Your doctor may decide to temporarily or permanently stop your treatment with Dapagliflozin/Metformin hydrochloride.
- **Necrotising fasciitis of the perineum** or Fournier’s gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus, seen very rarely.

Stop taking Dapagliflozin/Metformin hydrochloride and see a doctor as soon as possible if you notice any of the following serious or potentially serious effects:
- **Dehydration: loss of too much fluid from your body**, seen uncommonly (may affect up to 1 in 100 people).

These are signs of dehydration:
- very dry or sticky mouth, feeling very thirsty
- feeling very sleepy or tired
- passing little or no water (urine)
- fast heartbeat.
- **Urinary tract infection**, seen commonly (may affect up to 1 in 10 people).

These are signs of a severe infection of the urinary tract:
- fever and/or chills
- burning sensation when passing water (urinating)
- pain in your back or side.

Although uncommon, if you see blood in your urine, tell your doctor immediately.

Contact your doctor as soon as possible if you have any of the following side effects:
- **Low blood sugar levels (hypoglycaemia)**, seen very commonly (may affect more than 1 in 10 people) - when taking this medicine with a sulphonylurea or other medicines that lower the amount of sugar in your blood, such as insulin.

These are the signs of low blood sugar:
- shaking, sweating, feeling very anxious, fast heart beat
- feeling hungry, headache, change in vision
- a change in your mood or feeling confused.

Your doctor will tell you how to treat low blood sugar levels and what to do if you get any of the signs above. If you have symptoms of low blood sugar, eat glucose tablets, a high sugar snack or drink fruit juice. Measure your blood sugar if possible and rest.

Other side effects include:

Very common
- nausea, vomiting
- diarrhoea or stomach ache
- loss of appetite

Common
- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- back pain
- discomfort when passing water (urine), passing more water than usual or needing to pass water more often
- changes in the amount of cholesterol or fats in your blood (shown in tests)
- increases in the amount of red blood cells in your blood (shown in tests)
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment
- changes in taste
- dizziness
- rash
- decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Uncommon
- thirst
- constipation
- awakening from sleep at night to pass urine
- dry mouth
- weight decreased
- increases in creatinine (shown in laboratory blood tests) in the beginning of treatment
- increases in urea (shown in laboratory blood tests)

Very rare
- abnormalities in liver function tests, inflammation of the liver (hepatitis)
- redness of the skin (erythema), itching or an itchy rash (hives)

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 the Yellow Card Scheme, Website: 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 Dapagliflozin/Metformin hydrochloride

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the blister or carton after ‘EXP’. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dapagliflozin/Metformin hydrochloride contains
- The active substances are dapagliflozin and metformin hydrochloride (metformin HCl).
  Each Dapagliflozin/Metformin hydrochloride 5 mg/1,000 mg film-coated tablet (tablet) contains dapagliflozin propanediol monohydrate equivalent to 5 mg dapagliflozin and 1,000 mg metformin hydrochloride.
- The other ingredients are:
  - tablet core: hydroxypropyl cellulose (E463), microcrystalline cellulose (E460(i)), magnesium stearate (E470b), sodium starch glycolate (type A).
  - film-coating: polyvinyl alcohol (E1203), macrogol 3350 (E1521), talc (E553b), titanium dioxide (E171), iron oxide yellow (E172).

What Dapagliflozin/Metformin hydrochloride looks like and contents of the pack
Dapagliflozin/Metformin hydrochloride 5 mg/1,000 mg are 10.5 x 21.5 mm oval, yellow film-coated tablets. They have “5/1000” on one side and “1069” on the other side.
Dapagliflozin/Metformin hydrochloride 5 mg/1,000 mg film-coated tablets are available in packs of 56 film-coated tablets in non-perforated blisters.

Manufacturer
AstraZeneca AB
Gärtunavägen
SE-152 57 Södertälje
Sweden
Procured from within the EU and repackaged on behalf of the Product Licence Holder Mediwin PPIP Ltd., 13 Martello Enterprise Centre, Courtwick Lane, Littlehampton, BN17 7PA, UK.

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