

Package leaflet: Information for the patient

Mekinist® 0.5 mg film-coated tablets

(trametinib)

1000160611-x-xx-xx

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

What is in this leaflet

- What Mekinist is and what it is used for
- What you need to know before you take Mekinist
- How to take Mekinist
- Possible side effects
- How to store Mekinist
- Contents of the pack and other information

The name of your medicine is Mekinist 0.5 mg film-coated tablets but will be referred to as Mekinist throughout this leaflet.

Please note that the leaflet also contains information about other strengths.

1. What Mekinist is and what it is used for

Mekinist is a medicine that contains the active substance trametinib. It is used either on its own or in combination with another medicine containing dabrafenib to treat a type of skin cancer called melanoma that has spread to other parts of the body, or cannot be removed by surgery.

Mekinist in combination with dabrafenib is also used to prevent melanoma from coming back after it has been removed by surgery.

Mekinist in combination with dabrafenib is also used to treat a type of lung cancer called non-small cell lung cancer (NSCLC).

Both cancers have a particular change (mutation) in a gene called BRAF at the V600 position. This mutation in the gene may have caused the cancer to develop. Your medicine targets proteins made from this mutated gene and slows down or stops the development of your cancer.

2. What you need to know before you take Mekinist

Mekinist should only be used to treat melanomas and NSCLC with the BRAF mutation. Therefore, before starting treatment your doctor will test for this mutation.

If your doctor decides that you will receive treatment with the combination of Mekinist and dabrafenib, **read the dabrafenib leaflet carefully as well as this leaflet**.

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

Do not take Mekinist

- if you are allergic to trametinib or any of the other ingredients of this medicine (listed in section 6).

Check with your doctor if you think this applies to you.

Warnings and precautions

Talk to your doctor before taking your medicine. Your doctor needs to know if you:

- have any **liver problems**. Your doctor may take blood samples to monitor your liver function while you are taking this medicine.
- have or have ever had **kidney problems**.
- have or have ever had **lung or breathing problems**.
- have heart problems such as heart failure (which can cause shortness of breath, difficulty in breathing when lying down, swelling of the feet or legs) or problems with the way your heart beats. Your doctor should check your heart function before and during treatment.
- have eye problems including blockage of the vein draining the eye (retinal vein occlusion) or swelling in the eye which may be caused by fluid blockage (chorioretinopathy).

Before you take Mekinist in combination with dabrafenib your doctor needs to know if you:

- have had a different type of cancer other than melanoma or NSCLC**, as you may be at greater risk of developing non-skin cancers when taking Mekinist.

Check with your doctor if you think any of these may apply to you.

Conditions you need to look out for

Some people taking Mekinist develop other conditions which can be serious. You need to know about important symptoms to look out for.

Bleeding

Taking Mekinist or the combination of Mekinist and dabrafenib can cause serious bleeding including in your brain, the digestive system (such as stomach, rectum or intestine), lungs, and other organs, and can lead to death. Symptoms may include:

- headaches, dizziness, or feeling weak
- passing blood in the stools or passing black stools
- passing blood in the urine
- stomach pain
- coughing / vomiting up blood

Tell your doctor as soon as possible if you get any of these symptoms.

Fever

Taking Mekinist or the combination of Mekinist and dabrafenib may cause fever, although it is more likely if you are taking the combination treatment (see also section 4). In some cases, people with fever may develop low blood pressure, dizziness or other symptoms.

Tell your doctor immediately if you get a temperature above 38°C or if you feel a fever coming on while you are taking this medicine.

Heart disorder

Mekinist can cause heart problems, or make existing heart problems worse (see also “Heart conditions” in section 4) in people taking Mekinist in combination with dabrafenib.

Tell your doctor if you have a heart disorder. Your doctor will run tests to check that your heart is working properly before and during your treatment with this medicine. Tell your doctor immediately if it feels like your heart is pounding, racing, or beating irregularly, or if you experience dizziness, tiredness, light-headedness, shortness of breath or swelling in the legs. If necessary, your doctor may decide to interrupt your treatment or to stop it altogether.

Changes in your skin which may indicate new skin cancer

Your doctor will check your skin before you start taking this medicine and regularly while you are taking it. **Tell your doctor immediately** if you notice any changes to your skin while taking this medicine or after treatment (see also section 4).

Eye problems

You should have your eyes examined by your doctor while you are taking this medicine.

Tell your doctor immediately if you get eye redness and irritation, blurred vision, eye pain or other vision changes during your treatment (see also section 4).

Mekinist can cause eye problems including blindness. Mekinist is not recommended if you have ever had blockage of the vein draining the eye (retinal vein occlusion). Tell your doctor immediately if you get the following symptoms of eye problems: blurred vision, loss of vision or other vision changes, coloured dots in your vision or halos (seeing blurred outline around objects) during your treatment. If necessary, your doctor may decide to interrupt your treatment or to stop it altogether.

Liver problems

Mekinist, or the combination with dabrafenib, can cause problems with your liver which may develop into serious conditions such as hepatitis and liver failure, which may be fatal. Your doctor will monitor you periodically.

Signs that your liver may not be working properly may include:

- loss of appetite
- feeling sick (nausea)
- being sick (vomiting)
- pain in your stomach (abdomen)
- yellowing of your skin or the whites of your eyes (jaundice)
- dark-coloured urine
- itching of your skin

Tell your doctor as soon as possible if you get any of these symptoms.

Lung or breathing problems

Tell your doctor if you have any lung or breathing problems, including difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue. Your doctor may arrange to check your lung function before you start taking your medicine.

Muscle pain

Mekinist can result in the breakdown of muscle (rhabdomyolysis). **Tell your doctor** as soon as possible if you get any of these symptoms:

- muscle pain
- dark urine due to kidney damage

If necessary, your doctor may decide to interrupt your treatment or to stop it altogether.

→ **Read the information “Possible serious side effects” in section 4 of this leaflet.**

Hole in the stomach or intestine (perforation)

Taking Mekinist or the combination of Mekinist and dabrafenib may increase the risk of developing holes in the gut wall. Tell your doctor as soon as possible if you have severe abdominal pain.

Serious skin reactions

Serious skin reactions have been reported in people taking Mekinist in combination with dabrafenib. Tell your doctor immediately if you notice any changes to your skin (see section 4 for symptoms to be aware of).

Inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes

An inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes (sarcoidosis). Common symptoms of sarcoidosis may include coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints and tender bumps on your skin. Tell your doctor if you get any of these symptoms.

Immune system disorders

Mekinist in combination with dabrafenib may in rare instances cause a condition (haemophagocytic lymphohistiocytosis or HLH) in which the immune system makes too many infection-fighting cells, called histiocytes and lymphocytes. Symptoms may include enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities, and heart problems. Tell your doctor immediately if you experience multiple symptoms such as fever, swollen lymph glands, bruising or skin rash, at the same time.

Tumour lysis syndrome

If you experience the following symptoms, tell your doctor immediately as this can be a life-threatening condition: nausea, shortness of breath, irregular heartbeat, muscular cramps, seizures, clouding of urine, decrease in urine output and tiredness. These may be caused by a group of metabolic complications that can occur during treatment of cancer that are caused by the breakdown products of dying cancer cells (tumour lysis syndrome or TLS) and can lead to changes in kidney function (see also section 4).

Children and adolescents

Mekinist is not recommended for children and adolescents since the effects of Mekinist in people younger than 18 years old are not known.

Other medicines and Mekinist

Before starting treatment, tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines obtained without a prescription. Keep a list of the medicines you take, so you can show it to your doctor, nurse or pharmacist when you get a new medicine.

Mekinist with food and drink

It is important to take Mekinist on an empty stomach because food affects the way the medicine is absorbed into your body (see section 3).

Pregnancy, breast-feeding and fertility

Mekinist is not recommended for use during pregnancy.

- 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. Mekinist can harm the unborn baby.
- If you are a woman who could become pregnant, you must use reliable birth control (contraception) while you are taking Mekinist and for at least 16 weeks after you stop taking it.
- Birth control using hormones (such as pills, injections or patches) may not work as well if you are taking Mekinist in combination with dabrafenib. You need to use another effective method of birth control so you do not become pregnant while you are taking this combination of medicines. Ask your doctor, nurse or pharmacist for advice.
- If you do become pregnant while you are taking Mekinist, tell your doctor immediately.

Mekinist is not recommended while breast-feeding

It is not known whether the ingredients of Mekinist can pass into breast milk.

If you are breast-feeding, or planning to breast-feed, you must tell your doctor. It is recommended that you do not breast-feed while you are taking Mekinist. You and your doctor will decide whether you will take Mekinist or breast-feed.

Fertility – both men and women

Mekinist may impair fertility in both men and women.

Taking Mekinist with dabrafenib: Dabrafenib may permanently reduce male fertility. In addition, men who are taking dabrafenib may have a reduced sperm count, and their sperm count may not return to normal levels after they stop taking this medicine.

Prior to starting treatment with dabrafenib, talk to your doctor about options to improve your chances to have children in the future.

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

Driving and using machines

Mekinist can have side effects that may affect your ability to drive or use machines. Avoid driving or using machines if you feel tired or weak, if you have problems with your vision or if your energy levels are low. Descriptions of these effects can be found in other sections (see sections 2 and 4). Read all the information in this leaflet for guidance. Discuss with your doctor, nurse or pharmacist if you are unsure about anything. Your disease symptoms and treatment situation may also affect your ability to drive or use machines.

Mekinist contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Mekinist

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

How much to take

The usual dose of Mekinist either used alone or in combination with dabrafenib is one 2 mg tablet once a day. The recommended dose of dabrafenib, when used in combination with Mekinist, is 150 mg twice daily.

Your doctor may decide to lower the dose if you get side effects.

Don’t take more Mekinist than your doctor has recommended, since this may increase the risk of side effects.

How to take it

Swallow the tablet whole, with a full glass of water.

Take Mekinist once a day, on an empty stomach (at least 1 hour before a meal or 2 hours after a meal). This means that:

- after taking Mekinist, you must wait at least 1 hour before eating, or
- after eating, you must wait at least 2 hours before taking Mekinist.

Take Mekinist at about the same time each day.

If you take more Mekinist than you should

If you take too many tablets of Mekinist, contact your doctor, nurse or pharmacist for advice. If possible, show them the Mekinist pack and this leaflet.

If you forget to take Mekinist

If the missed dose is less than 12 hours late, take it as soon as you remember.

If the missed dose is more than12 hours late, skip that dose and take your next dose at the usual time. Then carry on taking your tablets at regular times as usual.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Mekinist

Take Mekinist for as long as your doctor recommends. Do not stop unless your doctor advises you to.

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

How should you take Mekinist in combination with dabrafenib

- Take Mekinist in combination with dabrafenib exactly as your doctor, nurse or pharmacist tells you. Do not change your dose or stop Mekinist or dabrafenib unless your doctor, nurse or pharmacist tells you to.
- Take **Mekinist once daily** and take **dabrafenib twice daily**. It may be good for you to get into the habit of taking both medicines at the same times each day. Mekinist should be taken with **either** the morning dose of dabrafenib **or** the evening dose of dabrafenib. The dabrafenib doses should be about 12 hours apart.
- Take Mekinist and dabrafenib on an empty stomach, at least one hour before or two hours after a meal. Take whole with a full glass of water.
- If you miss a dose of Mekinist or dabrafenib, take it as soon as you remember: Do not make up for missed doses and just take your next dose at your regular time:
 - If it is less than 12 hours to your next scheduled dose of Mekinist, which is taken once daily.
 - If it is less than 6 hours to your next scheduled dose of dabrafenib, which is taken twice daily.
- If you take too much Mekinist or dabrafenib, immediately contact your doctor, nurse or pharmacist. Take Mekinist tablets and dabrafenib capsules with you when possible. If possible, show them the Mekinist and dabrafenib pack with each leaflet.
- If you get side effects your doctor may decide that you should take lower doses of Mekinist and dabrafenib. Take the doses of Mekinist and dabrafenib exactly as your doctor, nurse or pharmacist tells you.

4. Possible side effects

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

Possible serious side effects

Heart conditions

Mekinist can affect how well your heart pumps blood. It is more likely to affect people who have an existing heart problem. You will be checked for any heart problems while you are taking Mekinist. Signs and symptoms of heart problems include:

- feeling like your heart is pounding, racing, or beating irregularly
- dizziness
- tiredness
- feeling light-headed
- shortness of breath
- swelling in the legs

Tell your doctor as soon as possible if you get any of these symptoms, either for the first time or if they get worse.

High blood pressure

Mekinist can cause new or worsening high blood pressure (hypertension). Your doctor or nurse should check your blood pressure during treatment with Mekinist. Call your doctor or nurse right away if you develop high blood pressure, your blood pressure worsens, or you have severe headache, light-headedness, or dizziness.

Bleeding problems

Mekinist can cause serious bleeding problems, especially in your brain or stomach. Call your doctor or nurse and get medical help right away if you have any unusual signs of bleeding, including:

- headaches, dizziness, or weakness
- coughing up of blood or blood clots
- vomit containing blood or that looks like “coffee grounds”
- red or black stools that look like tar

Eye (vision) problems

Mekinist can cause eye problems. Mekinist is not recommended if you have ever had a blockage of the vein draining the eye (retinal vein occlusion). Your doctor may advise an eye examination before you take Mekinist and while you are taking it. Your doctor may ask you to stop taking Mekinist or refer you to a specialist, if you develop signs and symptoms in your vision that include:

- loss of vision
- eye redness and irritation
- coloured dots in your vision
- halo (seeing a blurred outline around objects)
- blurred vision

Changes in your skin

Serious skin reactions have been reported in people taking Mekinist in combination with dabrafenib (frequency not known). If you notice any of the following:

- reddish patches on the trunk that are circular or target-shaped, with central blisters. Skin peeling. Ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- widespread rash, fever, and enlarged lymph nodes (DRESS-syndrome or drug hypersensitivity syndrome).
 - stop using the medicine and seek medical attention immediately**

Up to 3 in 100 people taking Mekinist in combination with dabrafenib may develop a different type of skin cancer called *cutaneous squamous cell carcinoma (cuSCC)*. Others may develop a type of skin cancer called *basal cell carcinoma (BCC)*. Usually, these skin changes remain local and can be removed with surgery and treatment with Mekinist and dabrafenib can be continued without interruption.

Some people taking Mekinist in combination with dabrafenib may also notice that new melanomas have appeared. These melanomas are usually removed by surgery and treatment with Mekinist and dabrafenib can be continued without interruption.

Your doctor will check your skin before you start taking dabrafenib, then check it again every month while you are taking dabrafenib and for 6 months after you stop taking it. This is to look for any new skin cancers.

Your doctor will also check your head, neck, mouth and lymph glands and you will have scans of your chest and stomach area (called CT scans) regularly. You may also have blood tests. These checks are to detect if any other cancer, including squamous cell carcinoma, develops inside your body. Pelvic examinations (for women) and anal examinations are also recommended before and at the end of your treatment.

Mekinist as monotherapy or in combination with dabrafenib can cause rash or acne-like rash. Follow your doctor’s instructions for what to do to help prevent rash. Tell your doctor or nurse as soon as possible if you get any of these symptoms for the first time or if they get worse.

Contact your doctor immediately if you get a severe skin rash with any of the following symptoms: blisters on your skin, blisters or sores in your mouth, peeling of your skin, fever, redness or swelling of your face, or soles of your feet.

Tell your doctor or nurse as soon as possible if you get any skin rash, or if you have a rash that gets worse.

Muscle pain

Mekinist can result in the breakdown of muscle (rhabdomyolysis). Tell your doctor or nurse if you have any new or worsening symptoms, including:

- muscle pain
- dark urine due to kidney damage

Lung or breathing problems

Mekinist can cause inflammation of the lung (pneumonitis or interstitial lung disease). Tell your doctor or nurse if you have any new or worsening symptoms of lung or breathing problems, including:

- shortness of breath
- cough
- fatigue

Immune system disorders

If you experience multiple symptoms such as fever, swollen lymph glands, bruising or skin rash, at the same time, tell your doctor immediately. These may be signs of a condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (haemophagocytic lymphohistiocytosis), see section 2 (frequency rare).

Tumour lysis syndrome

Tell your doctor immediately if you experience the following symptoms: nausea, shortness of breath, irregular heartbeat, muscular cramps, seizures, clouding of urine, decrease in urine output and tiredness. These may be signs of a condition resulting from a rapid breakdown of cancer cells which in some people may be fatal (tumour lysis syndrome or TLS), see section 2 (frequency not known).

Possible side effects in patients taking Mekinist alone

The side effects that you may see when you take Mekinist alone are as follows:

Very common side effects (may affect more than 1 in 10 people):

- High blood pressure (hypertension)
- Bleeding, at various sites in the body, which may be mild or serious
- Cough
- Shortness of breath
- Diarrhoea
- Feeling sick (nausea), being sick (vomiting)
- Constipation
- Stomach ache
- Dry mouth
- Skin rash, acne-like rash, redness of the face, dry or itching skin (see also “Changes in your skin” earlier in section 4)
- Unusual hair loss or thinning
- Lack of energy or feeling weak or tired
- Swelling of the hands or feet (oedema peripheral)
- Fever

Very common side effects that may show up in your blood tests

- Abnormal blood test results related to the liver

Common side effects (may affect up to 1 in 10 people):

- Inflammation of hair follicles in the skin
- Nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles
- Infection of the skin (cellulitis)
- Skin rash with pus-filled blisters (see also “Changes in your skin” earlier in section 4)
- Allergic reaction (hypersensitivity)
- Dehydration (low levels of water or fluid)
- Blurred vision
- Swelling around the eyes
- Eyesight problems (see also “Eye (vision) problems” earlier in section 4)
- Changes in how the heart pumps blood (left ventricular dysfunction) (see also “Heart conditions” earlier in section 4)
- Heart rate that is lower than the normal range and/or a decrease in heart rate
- Localised tissue swelling
- Inflammation of the lung (pneumonitis or interstitial lung disease)
- Sore mouth or mouth ulcers, inflammation of mucous membranes
- Reddening, chapping or cracking of the skin
- Red, painful hands and feet
- Swelling of the face
- Inflammation of the mucosa
- Feeling weak
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet and/or muscle weakness (peripheral neuropathy)

Common side effects that may show up in your blood tests:

- Decreased red blood cells (anaemia), abnormal test related to creatine phosphokinase, an enzyme found mainly in heart, brain, and skeletal muscle

Uncommon side effects (may affect up to 1 in 100 people):

- Swelling in the eye caused by fluid leakage (chorioretinopathy) (see also “Eye (vision) problems” earlier in section 4)
- Swelling of nerves at the back of the eye (papilloedema) (see also “Eye (vision) problems” earlier in section 4)
- Separation of the light-sensitive membrane in the back of the eye (the retina) from its supporting layers (retinal detachment) (see also “Eye (vision) problems” earlier in section 4).
- Blockage of the vein draining the eye (retinal vein occlusion) (see also “Eye (vision) problems” earlier in section 4)
- Heart pumping less efficiently, causing shortness of breath, extreme tiredness and swelling in ankles and legs (heart failure)
- A hole (perforation) in the stomach or intestines
- Inflammation of the intestines (colitis)
- Breakdown of muscle which can cause muscle pain and kidney damage (rhabdomyolysis)

Not known (frequency cannot be estimated from the available data):

- Irregular heartbeat (atrioventricular block)

Side effects when Mekinist and dabrafenib are taken together

When you take Mekinist and dabrafenib together you may get any of the side effects given in the lists above, although the frequency may change (increase or decrease).

You may also get **additional side effects due to taking dabrafenib** at the same time as Mekinist in the list below.

Tell your doctor as soon as possible if you get any of these symptoms, either for the first time or if they get worse.

Please read the dabrafenib Package Leaflet for details of the side effects you may get when taking this medicine.

The side effects that you may see when you take Mekinist in combination with dabrafenib are as follows:

Very common side effects (may affect more than 1 in 10 people):

- Nasal and throat inflammation
- Decreased appetite
- Headache
- Dizziness
- High blood pressure (hypertension)
- Bleeding, at various sites in the body, which may be mild or serious (haemorrhage)
- Cough
- Stomach ache
- Constipation
- Diarrhoea
- Feeling sick (nausea), being sick (vomiting)
- Rash, dry skin, itching, skin reddening
- Joint pain, muscle pain, or pain in the hands or feet
- Muscle spasms
- Lack of energy, feeling weak
- Chills
- Swelling of the hands or feet (oedema peripheral)
- Fever
- Flu-like illness

Very common side effects that may show up in your blood tests

- Abnormal blood test results related to the liver

Common side effects (may affect up to 1 in 10 people):

- Infection of the urinary system
- Skin effects including infection of the skin (cellulitis), inflammation of hair follicles in the skin, nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles, skin rash with pus-filled blisters, cutaneous squamous cell carcinoma (a type of skin cancer), papilloma (a type of skin tumour which is usually not harmful), wart-like growths, increased sensitivity of the skin to sun (see also “Changes in your skin” earlier in section 4)
- Dehydration (low levels of water or fluid)
- Blurred vision, eyesight problems, inflammation of the eye (uveitis)
- Heart pumping less efficiently
- Low blood pressure (hypotension)
- Localised tissue swelling
- Shortness of breath
- Dry mouth
- Sore mouth or mouth ulcers, inflammation of mucous membranes
- Acne-like problems
- Thickening of the outer layer of the skin (hyperkeratosis), patches of thick, scaly, or crusty skin (actinic keratosis), chapping or cracking of the skin
- Increased sweating, night sweats
- Unusual hair loss or thinning
- Red, painful hands and feet
- Inflammation of the fatty layer under the skin (panniculitis)
- Inflammation of the mucosa
- Swelling of the face
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet and/or muscle weakness (peripheral neuropathy)

Common side effects that may show up in your blood tests

- Low levels of white blood cells
- Decrease in number of red blood cells (anaemia), blood platelets (cells that help blood to clot), and a type of white blood cells (leukopenia)
- Low levels of sodium (hyponatraemia) or phosphate (hypophosphataemia) in the blood
- Increase in blood sugar level
- Increase in creatine phosphokinase, an enzyme found mainly in heart, brain, and skeletal muscle
- Increase in some substances (enzymes) produced by the liver

Uncommon side effects (may affect up to 1 in 100 people):

- Appearance of new skin cancer (melanoma)
- Skin tags
- Allergic reactions (hypersensitivity)
- Eye changes including swelling in the eye caused by fluid leakage (chorioretinopathy), separation of the light-sensitive membrane in the back of the eye (the retina) from its supporting layers (retinal detachment) and swelling around the eyes
- Heart rate that is lower than the normal range and/or a decrease in heart rate
- Inflammation of the lung (pneumonitis)
- Inflammation of pancreas
- Inflammation of the intestines (colitis)
- Kidney failure
- Inflammation of the kidneys
- Inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes (sarcoidosis)
- Irregular heartbeat (atrioventricular block)
- Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms, legs, face and neck, with a fever (signs of acute febrile neutrophilic dermatosis)

Rare side effects (may affect up to 1 in 1000 people)

- A hole (perforation) in the stomach or intestines

Not known (frequency cannot be estimated from the available data):

- Inflammation of the heart muscle (myocarditis) which can result in breathlessness, fever, palpitations and chest pain.
- Inflamed, flaky skin (exfoliative dermatitis)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Mekinist

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 bottle label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture. Keep the bottle tightly closed with the dessicant inside (small cylinder shaped container).

Once opened, the bottle may be stored for 30 days at not more than 30°C. If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Do not throw away 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 Mekinist contains

- The active substance is trametinib. Each film-coated tablet contains trametinib dimethyl sulfoxide equivalent to 0.5 mg of trametinib.
- The other ingredients are
 - Tablet: mannitol (E421), microcrystalline cellulose (E460), hypromellose (E464), croscarmellose sodium (E468), magnesium stearate (E470b), sodium laurilsulfate and colloidal silicon dioxide (E551).
 - Film coating: hypromellose (E464), titanium dioxide (E171), polyethylene glycol, iron oxide yellow (E172).

What Mekinist looks like and contents of the pack

The Mekinist 0.5 mg film-coated tablets are yellow, modified oval, biconvex, with the company logo debossed on one face and “TT” on the opposing face.

The film-coated tablets are supplied in opaque white plastic bottles with threaded plastic closures. One bottle contains 30 tablets.

The bottles also include a silica gel desiccant in a small cylinder shaped container. The desiccant must be kept inside the bottle and must not be eaten.

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder Orifarm UK Ltd., Ground Floor Suite A2, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ, UK

For any information about this medicine, please contact the Product Licence Holder on

www.orifarm.com/uk

Or phone: (+44) 1923 204333

Repacked by Orifarm Supply s.r.o., Palouky 1366, 253 01 Hostivice, Czech Republic

Manufactured by Novartis Pharma GmbH, Sophie-Germain-Straße 10, 90443 Nürnberg, Germany

Mekinist 0.5 mg film-coated tablets
PL 45985/0656

POM

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