

# MEKINIST®

trametinib (as dimethyl sulfoxide) tablets

## Consumer Medicine Information

### What is in this leaflet

**Please read this leaflet carefully before you start using MEKINIST.**

This leaflet answers some common questions about MEKINIST (trametinib). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date Consumer Medicine Information from [www.novartis.com.au](http://www.novartis.com.au).

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MEKINIST against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What MEKINIST is used for

MEKINIST tablets contain the active ingredient trametinib. MEKINIST belongs to a group of medicines called "selective MEK-inhibitors".

MEKINIST can be used by itself or in combination with another medicine called TAFINLAR

**If you are taking these two medicines together, read the full TAFINLAR Consumer Medicine Information as well as this one carefully.**

MEKINIST is used to:

- treat types of:
  - thyroid cancers called anaplastic thyroid cancer (ATC)
  - lung cancers called non-small cell lung cancer (NSCLC)
  - skin cancers called melanoma that have spread to other parts of the body.
- prevent melanoma from coming back after the melanoma has been removed by surgery.

All of these cancers have a change (mutation) in a gene called "BRAF" that may have caused the cancer to develop. MEKINIST targets proteins made from this changed gene and slows down or stops the development of your cancer.

**Ask your doctor, pharmacist, or nurse if you have any questions about how MEKINIST works or why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

MEKINIST should not be used in children and adolescents, under the age of 18 years because it is not known whether it is safe and effective in this younger group of patients.

This medicine is available only with a doctor's prescription.

It is not addictive.

### Before you take MEKINIST

Before you take MEKINIST, your doctor will take tumour tissue samples to check whether MEKINIST is suitable for you.

### When you must not take it

**Do not take MEKINIST if:**

- you have an allergy to trametinib (active ingredient) or to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

The expiry date refers to the last day of that month.

**If it has expired or is damaged, return it to your pharmacist for disposal.**

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Before you start to take it***

**If you are pregnant or breast-feeding, or think you may become pregnant or are planning to have a baby, ask your doctor, pharmacist or health care provider for advice before taking this medicine. Also, please read the section "Pregnancy" in this leaflet.**

Your doctor will discuss with you the potential risk(s) of taking MEKINIST during pregnancy or breast-feeding.

**Tell your doctor, healthcare provider, pharmacist, or nurse if you have allergies to any other medicines, foods, preservatives or dyes.**

They will want to know if you are prone to allergies.

**Tell them if you have or have had any of the following medical conditions:**

- **Heart problems**

Such as heart failure, so that you:

- Are short of breath
- Have difficulties breathing when lying down
- Have swelling of the feet or legs or
- Have problems with the way your heart beats.

Your doctor should check your heart function before you start taking MEKINIST and during treatment.

- **Eye problems**

Including:

- Sensation of flashing light, loss of vision (retinal detachment)
- Blockage of the vein draining the eye (retinal vein occlusion) or

- Swelling in the back of the eye which may be caused by fluid blockage (chorio-retinopathy).

Your doctor may arrange for you to have an eye examination before you take MEKINIST and while you are taking it.

- **Lung or breathing problems**

Including:

- Difficulty in breathing often accompanied by chest pain, fainting, rapid heart rate, bluish skin discoloration. Your doctor may arrange to check your lung function before you start taking MEKINIST
- Interstitial lung disease (ILD)
  - the group of diseases that affect the tissues and space around the air sacs of the lungs or
- Inflammation of the lung (pneumonitis).

- **Skin problems**

Including:

- Rash or
- Acne-like rash.

### ***If you are taking the combination of MEKINIST and TAFINLAR***

**Tell your doctor if you have an eye problem called uveitis.**

The symptoms of uveitis include:

- Eye redness and irritation
- Blurred vision
- Eye pain
- Increased sensitivity to light
- Floating spots before the eyes.

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

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Pregnancy***

**Do not take MEKINIST if you are pregnant or if you think that you may be pregnant.**

MEKINIST can harm your unborn baby.

**Ask your doctor, healthcare provider, pharmacist, or nurse for advice if you are planning to have a baby.**

Your doctor can discuss with you the risks and benefits involved.

**If you are a woman who could become pregnant, you must use effective birth control (contraception) while you are taking MEKINIST and for at least 16 weeks after you stop taking it.**

**If MEKINIST is taken in combination with TAFINLAR, non-hormonal contraception should be used.**

Birth control methods containing hormones (such as pills, injections, or patches) may not work as well while taking TAFINLAR.

**You need to use another effective method of birth control so you don't become pregnant while taking MEKINIST is taken in combination with TAFINLAR.**

**Ask your doctor, healthcare provider, pharmacist, or nurse about options for effective birth control or for advice.**

**If you do become pregnant while you're taking MEKINIST tell your doctor or nurse immediately.**

### ***Breast-feeding***

**If you are breast-feeding, or planning to breast-feed, you must tell your doctor.**

MEKINIST is not recommended while breast-feeding.

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

You and your doctor will decide whether you will take MEKINIST or breast-feed.

If you have not told your doctor about any of these things, tell them before you start taking MEKINIST.

### **Male patients**

Male patients (including those that have had a vasectomy) with female partners who are or may become pregnant should use condoms during sexual intercourse while on treatment and for at least 16 weeks after stopping MEKINIST.

### **Taking other medicines**

Tell your doctor, or healthcare provider, nurse, or pharmacist if you are taking, have recently taken, or might take any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## **How to take MEKINIST**

Follow all directions given to you by your doctor, healthcare provider, or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

### **How much to take**

The usual dose of MEKINIST is one 2 mg tablet once a day.

Depending on how you respond to MEKINIST, your doctor may decide that you should take a lower dose or interrupt treatment temporarily.

Don't take more MEKINIST than your doctor has recommended.

If you are aged 65 years or more, you can use MEKINIST at the same dose as for other adults.

### **When to take it**

Take MEKINIST once a day. Take it at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### **Take MEKINIST on an empty stomach**

It is important to take MEKINIST on an empty stomach. Food may affect the way the medicine is absorbed into your body.

MEKINIST should either be taken at least:

- **1 hour before eating**  
After taking MEKINIST, wait at least one hour before eating
- OR
- **2 hours after eating**  
After eating, wait at least two hours before taking MEKINIST.

### **How to take it**

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

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## **Taking MEKINIST together with TAFINLAR**

Swallow the MEKINIST tablet and the TAFINLAR capsule, with a full glass of water.

Take MEKINIST in combination with TAFINLAR exactly as your doctor tells you.

Do not change your dose, or stop MEKINIST in combination with TAFINLAR unless your healthcare provider tells you.

Take your once daily dose of MEKINIST at the same time each day, with EITHER the morning dose or the evening dose of TAFINLAR.

Take the first dose of TAFINLAR in the morning, and take the second dose of TAFINLAR in the evening, approximately 12 hours later.

Do NOT take:

- More than one dose of MEKINIST a day, or
- The morning and evening doses of TAFINLAR at the same time.

### **How long to take it**

Continue taking your medicine for as long as your doctor tells you.

This is a long term treatment, possibly lasting for months to years. Do not stop unless your doctor advises you to.

If you have any further questions about how long to take this medicine, ask your doctor or nurse.

### **If you forget to take it**

Do not take a double dose to make up for the dose that you missed.

### **MEKINIST taken alone**

If the missed dose is:

- Less than 12 hours late, take it as soon as you remember.
- More than 12 hours late, skip that dose and take your next dose at the usual time.

Then go back to taking your medicine as you would normally.

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

### **MEKINIST taken together with TAFINLAR**

If the missed dose of MEKINIST is:

- Less than 12 hours late, take it as soon as you remember.
- More than 12 hours late, skip that dose and take your next dose at the usual time.

Then carry on taking MEKINIST at regular times as usual.

Do not make up for missed doses.

If the missed dose of TAFINLAR is:

- **Less than 6 hours late, take it as soon as you remember**
- **More than 6 hours late, skip that dose and take the next dose at the usual time.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your doctor, nurse or pharmacist for some hints.**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that:**

- You may have taken too many MEKINIST tablets, or TAFINLAR capsules (if taking the combination), or if
- Somebody else may have accidentally taken your medicine(s).

**Do this even if there are no signs of discomfort or poisoning.**

You/they may need urgent medical attention.

**Take the medication pack(s) with you.**

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## **If you stop taking MEKINIST**

**Do not stop taking your medicine unless your doctor tells you to stop taking MEKINIST.**

Stopping your treatment with MEKINIST may cause your condition to become worse.

**If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or health care provider.**

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## **While you are using MEKINIST**

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### ***Things you must do***

**If you are about to be started on any new medicine remind your doctor and pharmacist that you are taking MEKINIST.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**Keep all of your doctor's appointments so that your progress can be checked.**

### ***Monitoring during your treatment***

Your doctor may do some tests from time to time to make sure that MEKINIST is working and to prevent unwanted side effects.

Your doctor may organize regular monitoring of your heart function during treatment with MEKINIST.

You may also have regular evaluations by an eye doctor (ophthalmologist) during treatment with this medicine.

During and after severe high fever events, some substances (enzymes) might be abnormally increased and your doctor will measure those and check that your kidneys are working properly.

### ***Conditions you may need to look out for***

Some people taking MEKINIST or MEKINIST and TAFINLAR together (combination treatment) develop other conditions which can be serious.

You need to know about important signs and symptoms to look out for while you're taking MEKINIST.

#### **FEVER (HIGH TEMPERATURE)**

Taking MEKINIST or the combination of MEKINIST with TAFINLAR may cause fever. Although, fever is more likely with the two medicines together.

Signs and symptoms of a fever may include:

- Temperature of 38°C or more
- Shivering/chills
- Thirst or dehydration
- Feeling dizzy, faint, or as if you're going to be sick.
- Low blood pressure

**Tell your doctor, or nurse immediately if you get a temperature of 38°C or above or if you feel a fever coming on (you have chills, night sweats or flu-like symptoms) while you are taking this medicine.**

They will carry out tests to find out if there are other causes for the fever and treat the problem with other medicines.

If you are taking MEKINIST or MEKINIST and TAFINLAR together you may be asked to stop taking it if your temperature is above 38°C, or if you have signs of fever (e.g. chills, night sweats or flu-like symptoms). If your fever is controlled; and only after you have had no symptoms for at least 24 hours, your doctor may recommend that you resume both treatments at a lower dose.

If the fever is very severe or keeps returning, your doctor may recommend that you stop taking both MEKINIST and TAFINLAR permanently.

### ***Things you must not do***

**Do NOT take MEKINIST with food. See "Take MEKINIST on an empty stomach."**

**Do NOT take MEKINIST to treat any other complaints unless your doctor tells you to.**

This medicine has been prescribed for only you.

**Do NOT give your medicine to anyone else, even if they have the same condition as you.**

It may harm them, even if the signs of illness are the same as yours.

**Do NOT stop taking your medicine or lower the dosage without first checking with your doctor.**

This may cause your condition to become worse.

### ***Things to be careful of***

**Be careful when driving or operating machinery until you know how MEKINIST affects you.**

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MEKINIST.**

Like all medicines, MEKINIST can cause side effects but not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

### ***Possible Serious Side Effects - when taking MEKINIST alone***

**STOP taking MEKINIST and tell your doctor, nurse, or pharmacist IMMEDIATELY if you get any of the following symptoms (either for the first time or if they get worse) during treatment with MEKINIST:**

- Headaches, dizziness, or weakness, coughing up of blood or blood clots, vomit containing blood or that looks like "coffee grounds", bleeding from nose, red or black stools that look like tar (signs of haemorrhage)
- Difficulty in breathing or swallowing, dizziness, swelling of the face lips, tongue or throat, severe itching of the skin, with a

red rash or raised bumps (signs of hypersensitivity reaction)

- Thirst, low urine output, weight loss, dry flushed skin, irritability (signs of dehydration)
- Loss of vision (sign of visual impairment)
- Fatigue, feeling full or bloated, heart palpitations, loss of appetite, nausea, reduced ability to exercise, shortness of breath, swelling (signs of left ventricular dysfunction)
- Slow heart-beat (sign of bradycardia)
- Cough, difficult or painful breathing, wheezing, pain in chest when breathing, fever (signs of pneumonitis)
- Swelling in the eye by fluid leakage causing a blurred vision (signs of chorioretinopathy)
- Sensation of flashing light, loss of vision (signs of retinal detachment)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (as signs of the heart muscle not pumping blood as well as it should and signs of cardiac failure)
- Severe stomach pain, nausea, and vomiting of blood, black or bloody stools (signs of gastrointestinal perforation in the stomach, small intestine, or bowel)
- Cramping diarrhoea with or without blood in stool, abdominal pain as signs of an inflammation of the inner lining of the colon (colitis)
- Blurring or loss of vision that is usually sudden in onset caused by blockage of small veins that carry blood away from the back of the eye (signs of retinal vein occlusion)
- Abnormal breakdown of muscle, causing pain, fever, red-brown urine (signs of rhabdomyolysis).

### ***Very common side effects - MEKINIST alone***

**Tell your doctor or pharmacist if you notice any of the following (that may affect more than 1 in 10 people):**

- Headache, dizziness, or other signs of high blood pressure
- Cough
- Short of breath, difficulty breathing
- Diarrhoea
- An increase in the volume, wateriness, or frequency of bowel movements (diarrhoea)
- Unpleasant feeling of needing to vomit, or unwillingness to eat (nausea)
- Uncomfortable, involuntary, forceful, throwing up of food (vomiting)
- Difficult or infrequent bowel movements (constipation)
- Stomach ache or abdominal pain
- Dry mouth
- Skin rash
- Rash, dry skin, acne-like problem (dermatitis acneiform)
- Dry skin
- Itching
- Unusual hair loss or thinning (alopecia)
- Feeling tired, weak or having lack of energy (fatigue)
- Swollen hands, ankles, or feet (peripheral oedema)
- Fever, temperature of 38°C or higher.

### ***Common side effects - MEKINIST alone***

**Tell your doctor or pharmacist if you notice any of the following that may affect up to 1 in 10 people.**

- Inflammation of hair follicles in the skin that causes itching (folliculitis)
- Nail disorders such as nail bed changes, nail pain, infection and

- swelling of the cuticles (paronychia)
- Hot, tender and red skin, sometimes with fever, chills, and inflammation caused by infection (cellulitis)
- Skin rash with pus-filled blisters (pustular rash)
- Tiredness, fatigue, pale skin (anaemia)
- Eyesight problems (blurred vision)
- Swelling of the eyelids and swelling around the eye (periorbital oedema)
- Tiredness, chest discomfort, light headedness pain, palpitations (ejection fraction decreased)
- Hard and painful swelling in the arms, legs, or other parts of the body (lymphoedema)
- Nose bleeds (epistaxis)
- Mouth sores, mouth ulcers, inflammation of gums (stomatitis)
- Skin chapped
- Skin reddening (erythema)
- Skin effects such as rash, wart-like growths, or redness and/or swelling and possibly peeling on the palms, fingers, and soles of the feet which may be accompanied by tingling sensation and burning pain (palmar-plantar erythrodysesthesia syndrome)
- Skin fissures
- Swelling of the face (face oedema)
- Pain, mouth sores, redness and swelling of airways or food pipe (mucosal inflammation)
- Unusual weakness (asthenia).

**Common side effects that may show up in your test results**

- Blood alkaline phosphatase (ALP) increased (bone function),
- Some elevated liver function enzymes (ALT and AST)

- Abnormal kidney blood test result as a sign of impaired muscle health (blood creatine phosphokinase increased).

**Uncommon side effects - MEKINIST**

**Tell your doctor or pharmacist if you notice any of the following (that may affect up to 1 in 100 people).**

- Blurred vision as a sign of swelling of the optic disk (papilloedema)
- Cough, difficulty breathing, painful breathing (ILD).

**Possible side effects - when taking MEKINIST with TAFINLAR**

**Refer to the TAFINLAR Consumer Medicine Information for possible side effects and important signs and symptoms to look out for, such as fever, skin problems and eye problems.**

When you take MEKINIST and TAFINLAR together you may get any of the side effects in the previous lists, although the frequency may change (increase or decrease).

**STOP taking MEKINIST and tell your doctor, nurse, or pharmacist IMMEDIATELY if you get any of the following symptoms (either for the first time or if they get worse) during treatment with MEKINIST.**

- Fever, chills, sore throat or mouth ulcers due to infections as signs of a low level of a type of white blood cells (signs of neutropenia)
- Generalized swelling (oedema includes generalized and peripheral oedema)
- Tiredness, fatigue, pale skin (anaemia)
- Fever, chills, sore throat or mouth ulcers due to infections as signs of a low level of white blood cells (leukopenia)
- Abnormal growth of cancerous cells of the skin (signs of cutaneous squamous cell

carcinoma (cuSCC) including SCC of the skin, SCC in situ (Bowen's disease), keratoacanthoma)

- Spontaneous bleeding or bruising (signs of thrombocytopenia)
- Sensation of flashing light, loss of vision (signs of retinal detachment)
- Acute severe upper stomach pain (sign of pancreatitis acute)
- Severely decreased urine output (signs of renal failure)
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration (signs of pulmonary embolism)
- High or low urine output, drowsiness, confusion, or nausea as signs of an inflamed kidney (tubulointerstitial nephritis)
- Abnormal breakdown of muscle, causing pain, fever, red-brown urine (signs of rhabdomyolysis)
- Painful red eye (sign of uveitis).
- Change in size or colour of a mole or a new skin lesion (new primary melanoma)
- Severe upper stomach pain (sign of pancreatitis)
- High or low urine output, drowsiness, confusion, or nausea as signs of an inflamed kidney (nephritis)
- Severely decreased urine output (sign of acute renal failure)
- Serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling, with or without fever, which may be possible signs of Stevens-Johnson syndrome.
- Serious skin reactions such as widespread rash, fever, and enlarged lymph nodes (which may be signs of drug reaction with eosinophilia and systemic symptoms [DRESS]).
- Chest pain, sudden shortness of breath, trouble breathing, pain in your legs with or without swelling, swelling in your arms

and legs, or a cool, pale arm or leg. These may be symptoms of a blood clot.

- Fever, swollen glands, bruising or skin rash at the same time. This may be signs of haemophagocytic lymphohistiocytosis or HLH, a condition in which the immune system makes too many infection-fighting cells, called histiocytes and lymphocytes.

### **Very common side effects when taking MEKINIST with TAFINLAR**

**Tell your doctor or pharmacist if you notice any of the following (that may affect more than 1 in 10 people).**

- Urinary tract infection
- Sore throat and runny nose (nasopharyngitis)
- Decreased appetite
- Tiredness, confusion, muscle twitching, convulsions (hyponatremia)
- Headache
- Dizziness
- Skin reddening (erythema)
- Thickening of the outer layers of the skin (hyperkeratosis also including actinic keratosis (thick scaly crusty skin), seborrheic keratosis (waxy, "pasted-on-the-skin" skin growths) and keratosis pilaris (rough, slightly red bumps on light skin and brown bumps on darker skin))
- Muscle spasms
- Joint pain (arthralgia)
- Muscle pain (myalgia)
- Pain in the hands or feet (pain in extremity)
- Excessive thirst, high urine output, dark urine, increase appetite with weight loss, dry flushed skin, irritability as signs of high level of sugar (glucose) in the blood (signs of hyperglycaemia)
- Dizziness, light-headedness (hypotension)

- Feeling weak, sick, and tired (fatigue including asthenia and malaise)
- Chills
- Tiredness, chills, sore throat, joints or muscles aching (influenza-like illness)

### **Very common side effects that may show up in your test results**

- High levels of the following enzymes:
  - blood alkaline phosphatase (AP) increased
  - alanine aminotransferase (ALT) increased (liver function)
  - aspartate aminotransferase (AST) increased (liver function).

### **Common side effects when taking MEKINIST with TAFINLAR**

- Warts (papilloma including skin papilloma)
- Skin tags (acrochordon)
- Low phosphorus in the blood (hypophosphatemia)
- Night sweats
- Skin lesion
- Skin fissures
- Excessive sweating (hyperhidrosis)
- Tender or painful bumps below the surface of the skin (panniculitis)
- Increased sensitivity of the skin to sun (photosensitivity).

### **Common side effects that may show up in your test results**

- Abnormal liver blood tests (gamma-glutamyltransferase increased)

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

### **Uncommon side effects when taking MEKINIST with TAFINLAR**

- Inflammatory disease mainly affecting the skin, lungs and eyes (sarcoidosis)

### **Frequency unknown when taking MEKINIST with TAFINLAR**

Multiple symptoms such as fever, swollen glands, bruising, or skin rash, occurring at the same time (haemophagocytic lymphohistiocytosis or HLH)

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## **After using MEKINIST**

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### **Storage**

**Keep MEKINIST tablets in the refrigerator at between 2°C and 8°C, where children cannot see or reach it.**

Whilst in use, the bottle may be stored out of the refrigerator for a maximum of 30 days. Keep it where children cannot reach it. A locked cupboard at least one and half metres above the ground is a good place to store medicines.

**Do NOT store MEKINIST or any other medicine:**

- In the bathroom or near a sink.
- On a window sill or in the car.

Heat and dampness can destroy some medicines.

**Keep the tablets in the bottle until it is time to take a dose.**

**Do not remove the desiccant. Keep the bottle tightly closed between doses.**

MEKINIST needs protection from light and moisture. If you take the tablets out of the bottle or remove the desiccant, they may not keep well.

## Disposal

If the packaging is torn or shows signs of tampering when you received it, return it to the pharmacist.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Do not throw MEKINIST in the general household rubbish or flush it down the toilet.

It may end up in landfill or enter waterways affecting the environment or marine life.

Do not keep old medicines because you think you may need them in the future.

Keeping any unwanted or expired medications runs the risk of unintentional poisonings.

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## Product description

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### **What MEKINIST tablets look like**

MEKINIST tablets are supplied in two strengths and are available in plastic bottles containing 30 tablets. The bottle has a child resistant closure and also contains a desiccant.

#### **0.5 mg tablets**

Yellow, modified oval, biconvex, film-coated tablets with 'GS' debossed on one face and 'TFC' on the opposite face; or

Yellow, ovaloid, biconvex, unscored, film-coated tablets with the Novartis logo on one side and 'TT' on the other side.

#### **2 mg tablets**

Pink, round, biconvex, film-coated tablets with 'GS' debossed on one face and 'HMJ' on the opposite face; or

Pink, round, biconvex, unscored, film-coated tablets with the Novartis logo on one side and 'LL' on the other side.

## Ingredients

Each MEKINIST tablet contains trametinib dimethyl sulfoxide, equivalent to 0.5 mg or 2 mg per tablet as the active ingredient.

The tablets also contain the following ingredients:

- Mannitol (E421)
- Microcrystalline cellulose (E460(i))
- Hypromellose (E464)
- Croscarmellose sodium
- Magnesium stearate (vegetable source) (E572)
- Sodium lauryl sulphate (E487)
- Colloidal anhydrous silica
- Titanium dioxide (E171)
- Polyethylene glycol

#### **0.5 mg tablet only**

The 0.5 mg tablet also contains:

- Iron oxide yellow CI 77492 (E172).

#### **2 mg tablet only**

The 2 mg tablet also contains:

- Polysorbate 80 (E433)
- Iron oxide red CI 77491 (E172)

MEKINIST tablets do not contain lactose, sucrose, gluten, tartrazine, or any other azo dyes.

- AUST R 205917: MEKINIST trametinib 0.5 mg (as dimethyl sulfoxide) tablet
- AUST R 205919: MEKINIST trametinib 2 mg (as dimethyl sulfoxide) tablet

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## Sponsor

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MEKINIST is supplied in Australia by:

**Novartis Pharmaceuticals  
Australia Pty Limited**

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