

MEKINIST[®]

Trametinib (as dimethyl sulfoxide) 0.5 mg, and 2 mg tablets

NZ 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.

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 leaflet from www.medsafe.govt.nz.

Those 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, nurse, or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MEKINIST is used for?

MEKINIST tablet contain the active ingredient trametinib. It 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 medicines together, please read the 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 mutated gene and slows down or stops the development of your cancer.

Ask your doctor, healthcare provider, 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 is not recommended for use in children or adolescents under the age of 18 years because it is not known whether it is safe and effective in these younger patients.

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

It is not addictive.

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 are pregnant (see "Pregnancy"), or
- 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
- It is after the expiry date printed on the pack. The expiry date refers to the last day of that month
- The packaging is torn or shows signs of tampering. 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 the potential risk(s) of taking MEKINIST during pregnancy or breast-feeding.

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

Tell your doctor, healthcare provider, pharmacist, or nurse if you have allergies to any other medicines, food, 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 (chorioretinopathy).

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

- **If you have or have ever had any kidney problems.**
 - **Lung diseases, including**
 - 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 disease (pneumonitis).
- Your doctor may arrange to check your lung function before you start taking MEKINIST.
- **Any 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 and breast-feeding

Tell your doctor, or nurse if you are pregnant or breast-feeding,

think you may be pregnant, or plan to become pregnant.

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

MEKINIST taken alone and in combination with TAFINLAR is not recommended for use during pregnancy.

MEKINIST can harm an unborn baby.

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 MEKINIST.

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

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

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.

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

Taking other medicines

Tell your doctor, healthcare provider, nurse, or pharmacist if you are taking 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.

How to take MEKINIST

Always follow all directions given to you by your doctor, healthcare provider, nurse, or pharmacist.

Their directions may differ from the information contained in this leaflet.

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

When to take it

Take MEKINIST once a day on an empty stomach.

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

MEKINIST should be taken at least:

- **1 hour before eating**
- OR**
- **2 hours after eating.**

Take your medicine 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.

If taking MEKINIST BEFORE something to eat or drink, take it and then wait at least one (1) hour before having food or drink.

If taking MEKINIST AFTER eating a meal or snack, wait at least two (2) hours before taking it.

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.

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

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

How to take it

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

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 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 PER DAY.

If you take too much MEKINIST or TAFINLAR, call your doctor or go to the nearest hospital right away.

How long to take it

This is a long term treatment, possibly lasting for months to years.

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

Do not stop taking it 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

MEKINIST taken alone

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

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.

MEKINIST taken together with TAFINLAR

If the miss a dose of MEKINIST or TAFINLAR, take it as soon as you remember.

Do not make up for missed doses.

Then take your next dose at your regular time. If it is less than:

- 12 hours late to your next scheduled dose of MEKINIST, which is taken once daily.
- 6 hours to your next scheduled dose of TAFINLAR, which is taken twice daily.

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

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)

In New Zealand, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), 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 your medication pack(s) with you.

While you are using MEKINIST

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, nurses, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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 will organize regular monitoring of your heart function before and during treatment with MEKINIST.

You may also have regular evaluations by a specialist eye doctor before and during treatment with MEKINIST.

During and after severe high fever events some substances (enzymes) might be abnormally increased and

your doctor might measure those and check that your kidneys are working properly.

Your eyes should be evaluated by a specialist eye doctor before and during treatment with MEKINIST.

Signs 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 if you are taking the combination treatment. Signs and symptoms of fever include:

- High temperature (38.0°C or above)
- Shivering/chills
- Thirst or dehydration
- Feeling dizzy, faint, or as if you are going to be sick
- Low blood pressure.

Tell your doctor, or nurse immediately if you get a temperature of 38.0°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.

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.

- **Heart Disorder**

MEKINIST can affect how well your heart pumps with each beat, can cause heart problems, or make existing heart problems worse. People may be more likely to develop this side effect if they have an existing heart problem.

Tell your doctor immediately if you feel:

- Like your heart is pounding, racing, or beating irregularly;
- Dizziness, tiredness, lightheaded, shortness of breath or 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.

If necessary, your doctor may decide to interrupt your treatment temporarily or stop it altogether. If you are taking the combination treatment, you may be allowed to continue treatment as normal with TAFINLAR.

- **Eye Problems**

MEKINIST can cause eye problems including blindness. MEKINIST is not recommended if you have ever had a blockage of the vein draining the eye (retinal vein occlusion).

Tell your doctor immediately if you get these following symptoms of eye problems:

- Blurred vision
- Loss of vision or other vision changes
- Eye redness and irritation
- See colour dots, halos (seeing blurred outline around

objects) during your treatment.

If you develop any of these symptoms, your doctor or nurse will arrange for a full eye examination. If necessary, your doctor may decide to interrupt your treatment temporarily or stop it altogether. If you are taking the combination treatment, you may be allowed to continue treatment as normal with TAFINLAR.

- **Serious skin adverse reactions**

Tell your doctor immediately if you get any of these symptoms during treatment with MEKINIST:

- 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.
- widespread rash, fever, and enlarged lymph nodes (which may be signs of drug reaction with eosinophilia and systemic symptoms [DRESS]).

- **Skin rash or blisters**

Severe skin reactions (rash) can happen while taking MEKINIST, including rash, acne-like rash, or other skin problems.

Talk to your doctor if you get a skin rash.

Depending on how bad your rash is, you may be asked to interrupt treatment, or take your treatment at a lower dose because of the rash.

Talk to 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, hands, or soles of your feet.

- **Immune system disorders**

Tell your doctor immediately if you experience multiple symptoms while on treatment such as:

- 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.

- **Metabolic disorders**

Tell your doctor immediately if you experience multiple symptoms such as:

- irregular heartbeat, decrease in urine output, confusion, severe nausea and vomiting, shortness of breath, muscle cramps or spasms at the same time which may be signs of tumour lysis syndrome or TLS, a condition resulting from a fast breakdown of cancer cells.

- **Blood clots**

Tell your doctor, pharmacist or healthcare provider immediately if you get any of these symptoms during treatment with MEKINIST, as these may be signs of a blood clot in the veins of the arm or leg, in the lung or other parts of the body:

- 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

- **Bleeding problems**

MEKINIST, when taken in combination with TAFINLAR, can cause serious bleeding

problems, especially in your brain or stomach, and can lead to death.

Call your doctor or nurse and get medical help right away if you have any unusual signs of bleeding, including:

- Headaches, dizziness, or feeling weak;
- Coughing up blood or blood clots;
- Vomiting blood or your vomit looks like "coffee grounds";
- Bleeding from the nose
- Passing red or black stools that look like tar.

Things you must not do

Do NOT take MEKINIST with food. You must take it on an empty stomach.

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

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. This medicine has been prescribed for only you.

Do NOT stop taking your medicine or lower the dosage without 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.

Side effects

Tell your doctor, nurse, 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 inform your doctor, nurse, or pharmacist immediately if you experience any serious side effects, including any of the following symptoms (either for the first time or if they get worse):

- Any lung or breathing problems, including difficulty in breathing often accompanied by:
 - chest pain, fainting, rapid heart rate, bluish skin discolouration
 - difficulty in swallowing
- High fever which may be accompanied by severe chills, dehydration and low blood pressure
- 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
- Loss of vision (sign of visual impairment)
- Blurred vision
- Swelling in the eye by fluid leakage causing blurred vision (signs of chorioretinopathy)
- Blockage of the vein draining the eye
- Sensation of flashing light, loss of vision

- 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)
- 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)
- Headaches, dizziness, or weakness, coughing up of blood or blood clots, vomit containing blood or vomit that looks like “coffee grounds”, bleeding from nose, red or black stools that look like tar (signs of haemorrhage)
- Cough, difficult or painful breathing, wheezing, pain in chest when breathing, fever (signs of pneumonitis)
- Crushing stomach pain, nausea, and blood loss
- Diarrhoea, abdominal pain, and fever
- Abnormal breakdown of muscle, causing pain, fever, red-brown urine (signs of rhabdomyolysis)
- Fever, swollen glands, bruising or skin rash at the same time
- Irregular heartbeat (atrioventricular block or bundle branch block)

Possible side effects when taking MEKINIST alone

Very common side effects when taking 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 as signs of high blood pressure (hypertension)
- Cough

- Shortness of breath, laboured breathing, chest tightness
- Diarrhoea
- Feeling sick (nausea)
- Being sick (vomiting)
- Constipation
- Stomach ache or abdominal pain
- Dry mouth
- Rash
- Skin 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)
- Bleeding, at various sites in the body, which may be mild or serious
- Fever, temperature of 38.0°C or higher.

Common side effects - when taking 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 and chills, and inflammation caused by infection (cellulitis)
- Inflammation of the skin 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)
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet/muscle weakness (peripheral neuropathy)

Common side effects that may show up in your test results

- Low levels of white or red blood cells
- Some high liver function enzymes.

Uncommon side effects - when taking MEKINIST alone

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).
- Irregular heartbeat (atrioventricular block or bundle branch block)

Additional possible side effects - when taking MEKINIST with TAFINLAR

Refer to the Consumer Medicine Information for TAFINLAR for the 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 shown in the previous lists, although the frequency may change (increase or decrease).

Possible serious side effects - when taking MEKINIST with TAFINLAR

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

- 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 low level of white blood cells (signs of neutropenia or 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 acute renal failure)
- 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, as these may be signs of a blood clot in the veins of the arm or leg, in the lung or other parts of the body.
- 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)
- Irregular heartbeat (atrioventricular block or bundle branch block)
- multiple symptoms such as fever, swollen glands, bruising, or skin rash, occurring at the same time (haemophagocytic lymphohistiocytosis or HLH)
- multiple symptoms such as irregular heartbeat, decrease in urine output, confusion, severe nausea and vomiting, shortness of breath, muscle cramps or spasms, occurring at the same time (tumour lysis syndrome or TLS)

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 the extremity)
- Excessive thirst, high urine output, dark urine, increase appetite with weight loss, dry flushed skin, and irritability as signs of high level of sugar (glucose) in the blood (signs of hyperglycaemia)
- Dizziness, light-headedness (hypotension)
- Feeling weak, sick, and tired (asthenia including malaise and fatigue)
- Chills
- Tiredness, chills, sore throat, joint or muscles aching (influenza-like illness)
- Weight decreased.

Very common side effects that may show up in your test results - when taking MEKINIST with TAFINLAR

- High levels of some liver function enzymes.

Common side effects - when taking MEKINIST with TAFINLAR

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

- Warts (papilloma or lumpy growths in the skin)
- Waxy, scaly, slightly raised or “pasted-on-the-skin” skin growths
- Skin tags (harmless, soft, skin-coloured growth that hangs from the surface of the skin on a thin piece of tissue called a stalk)
- 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)
- Thickening of the skin (hyperkeratosis)
- Muscle spasms
- Tiredness, chills, sore throat, joint or muscles aching (influenza-like illness)
- Weight increased.
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet/muscle weakness (peripheral neuropathy)
- Irregular heartbeat (atrioventricular block or bundle branch block)

Common side effects that may show up in your blood tests - when taking MEKINIST with TAFINLAR

- High level of some substances produced by the liver
- Low levels of phosphorous.

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)
- multiple symptoms such as irregular heartbeat, decrease in urine output, confusion, severe nausea and vomiting, shortness of breath, muscle cramps or spasms, occurring at the same time (tumour lysis syndrome or TLS)
- 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 or Sweet’s syndrome).

Tell your doctor, nurse, or pharmacist if you notice anything else that is making you feel unwell.

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

After using MEKINIST

Storage

Keep MEKINIST tablets:

- In the refrigerator (at between 2°C to 8°C).

The bottle may be stored out of the refrigerator for no more than 30 days.

- Where children see or cannot reach them.

A locked cupboard at least one and half metres above the ground

is a good place to store medicines.

- In the bottle until it is time to take a dose.

Close the bottle lid tightly afterwards and keep it like this until it is time to take the next tablet.

Do NOT remove the desiccant from the bottle. Keep the desiccant in the bottle during use.

Light, heat, and dampness will deteriorate this medicine.

Do NOT store MEKINIST (or any other medicine):

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

Disposal

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 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 medicines runs the risk of accidental poisonings.

Product description

What they look like

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

Each tablet also contains the following excipients:

- Mannitol (E421)
- Microcrystalline cellulose (E460(i))
- Hypromellose (E464)
- Croscarmellose sodium (E468)
- Magnesium stearate (E572)
- Sodium lauryl sulphate (E487)
- Silica - colloidal anhydrous
- Titanium dioxide (E171)
- Polyethylene glycol (E1520).

0.5 mg tablet only

The 0.5 mg tablet also contains:

- Iron oxide yellow (E172).

2 mg tablet only

The 2 mg tablet also contains:

- Iron oxide red (E172)
- Polysorbate 80 (E433).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

MEKINIST is supplied in New Zealand by:

NOVARTIS New Zealand Limited

PO Box 99102, Newmarket
Auckland 1149

Telephone 0800 354 335

® = Registered Trademark

This leaflet was prepared in May 2024 based on the currently approved data sheet for this product.

Internal document code
(mek290524cNZ) based on DS
(mek290524iNZ)