TAFINLAR®

dabrafenib (as mesilate) capsules

NZ Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using TAFINLAR.

This leaflet answers some common questions about TAFINLAR.

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.

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 TAFINLAR 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 TAFINLAR is used for

TAFINLAR capsules contain the active substance dabrafenib, which belongs to a group of medicines called "Selective BRAF-inhibitors".

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

If you are taking these medicines together, please read the MEKINIST Consumer Medicine Information as well as this one carefully.

TAFINLAR is a medicine used to:

- Treat types of:
  - Skin cancers called melanoma
  - Thyroid cancers called anaplastic thyroid cancer (ATC)
  - lung cancers called non-small cell lung cancer (NSCLC)

  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 changes (mutations) in a gene called "BRAF" that may have caused the cancer to develop.

TAFINLAR targets proteins made from this mutated BRAF gene and slows down or stops the development of your cancer.

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

Your doctor may have prescribed it for another reason.

TAFINLAR is not recommended for use in children and 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 TAFINLAR

Your doctor will take tumour tissue samples to check whether TAFINLAR is suitable for you.

Your doctor will check your skin before you start taking TAFINLAR, then check it during your treatment.

When you must not take it

Do not take TAFINLAR if:

- You are pregnant (see Pregnancy), or
- You have an allergy to dabrafenib mesilate (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.
- The expiry date has passed.

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

- The packaging is torn or shows signs of tampering when you received it.

If the pack 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

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.

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 TAFINLAR during pregnancy or breast-feeding.

If you do become pregnant while you are taking TAFINLAR, tell your doctor immediately.

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

- **Liver problems**

  Your doctor may take blood samples to monitor your liver function while you are taking TAFINLAR.
- **Kidney problems**

  Either now or in the past.

If you are taking the combination of TAFINLAR and MEKINIST

Tell your doctor, or healthcare provider if you have any of the following conditions:

- **Heart problems**

  Such as heart failure or problems with the way your heart beats.
- **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);
- **Any lung or breathing problems**

  Including difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue
- **Any skin problems**

  Including rash or acne-like rash.

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

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

Pregnancy

TAFINLAR alone or in combination with MEKINIST are not recommended during pregnancy.

If you do become pregnant while you are taking TAFINLAR, tell your doctor immediately.

TAFINLAR may harm your unborn baby.

Tell your doctor, healthcare provider, pharmacist, or nurse if you are planning to become pregnant.

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

If you are a woman who could become pregnant, you must use effective birth control (contraception) while you are taking TAFINLAR and for:

- 14 days after you stop taking it

OR

- At least 16 weeks following the last dose of MEKINIST (when taken in combination with TAFINLAR).

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

Use another effective method of birth control so you do not become pregnant while you are taking TAFINLAR.

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

If you are a man taking this medicine

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 2 weeks after stopping TAFINLAR.

If taking TAFINLAR in combination with MEKINIST, male patients should use condoms during sexual intercourse while on treatment and for at least 16 weeks after stopping the combination.

You may have reduced sperm count while you are taking this medicine. Your sperm count may not return to normal levels after you stop taking TAFINLAR.

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

Breast-feeding

TAFINLAR is not recommended while breast-feeding.

If you are breast-feeding or planning to breast-feed, you must tell your doctor, pharmacist, healthcare provider or nurse.

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

You and your doctor will decide if you will take TAFINLAR or breast-feed.

If you have not told your doctor about any of the above, tell him/her before you start taking TAFINLAR.

Taking other medicines

Tell your doctor, healthcare provider, pharmacist, or nurse, 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.

Some medicines may affect how TAFINLAR works, or make it more likely that you will have side effects. TAFINLAR can also affect how some other medicines work. These include:

- Birth control using hormones such as pills, injections, or patches;
- Warfarin, a medicine used to prevent blood clots;
- Some medicines to treat fungal infections, such as ketoconazole, itraconazole, voriconazole, posaconazole;
- Some antibiotic medicines, such as clarithromycin, telithromycin or rifampicin;
- Some medicines that suppress the immune system;
- Some medicines that reduce stomach acid, such as:
  - proton pump inhibitors (e.g. omeprazole esomeprazole, rabeprazole, pantoprazole, or lansoprazole);
  - H2 agonists or blockers (e.g. ranitidine, cimetidine, famotidine, or nizatidine); or
  - Antacids (e.g. containing aluminium hydroxide, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium trisilicate, or sodium bicarbonate).
- Some medicines used to lower fats (lipids) in the blood stream, such as gemfibrozil;
- Some anti-inflammatory medicines such as dexamethasone;
- Some medicines used to treat HIV, such as ritonavir, saquinavir and atazanavir;
- Some medicines used to treat seizures (epilepsy), such as phenytoin, phenobarbital, or carbamazepine;
- Some anti-depressant medicines such as nefazodone or the herbal medicine St John's wort (Hypericum perforatum)
- Some medicines used to treat high levels of cholesterol such as rosuvastatin.

Tell your doctor, healthcare provider, pharmacist, or nurse if you are taking any of these (or if you are not sure whether your medicine is one of the medications listed above).

Your doctor may decide to adjust your dose.

Keep a list of medicines you take, so you can show it to your doctor, pharmacist or healthcare provider when you get a new medicine.

They have more information on medicines to be careful with or avoid while taking this medicine.

How to take TAFINLAR

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

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

If you do not understand the instructions on the box or bottle, ask them for help.

How much to take

The usual total daily dose of TAFINLAR is 300 mg, taken as 150 mg taken on an empty stomach twice each day, as either:

- Two 75 mg capsules

  OR

- Three 50 mg capsules.

Depending on how you respond to TAFINLAR, your doctor may prescribe you a lower dose or interrupt temporarily the treatment. If you get side effects, your doctor may decide that you should take a lesser dose.

Do not take any more TAFINLAR than your doctor has recommended.

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

When to take it

Take the first 150 mg dose of TAFINLAR in the morning and take the second 150 mg dose of TAFINLAR in the evening, approximately 12 hours later.

The doses must be about 12 hours apart.

Take the morning and evening doses at about the same time each morning and evening.

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

Take TAFINLAR on an empty stomach.

It is important to take TAFINLAR on an empty stomach. Food may affect the way the medicine is taken up (absorbed) into your body.

TAFINLAR should be taken either at least:

- **1 hour before eating**

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

OR

- **2 hours after eating**

  If taking TAFINLAR AFTER eating a meal or having a drink, wait at least two (2) hours before taking TAFINLAR.

How to take it

Swallow each capsules whole, with a full glass of water. Take the capsules one after the other, unless your doctor has advised a lower dose.

After taking TAFINLAR, wait at least 1 hour before eating.

Taking this medicine in combination with MEKINIST tablet

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

DO NOT TAKE MORE THAN ONE DOSE OF MEKINIST PER DAY.

Take the MEKINIST tablet at the same time each day, with EITHER the morning or the evening dose of TAFINLAR capsules.

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

DO NOT TAKE THE MORNING AND EVENING DOSES OF TAFINLAR AT THE SAME TIME.

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 change your dose or stop TAFINLAR in combination with MEKINIST unless your doctor tells you.

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.

If you have any further questions about how long to take TAFINLAR, 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.

If the missed dose is:

- Less than 6 hours late, take it as soon as you remember;
- More than 6 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.

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 National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to the nearest hospital if you think that:

- You may have taken too many capsules of TAFINLAR, or MEKINIST tablet (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 may need urgent medical attention.

Take your medication packs with you.

If you stop taking TAFINLAR

Do not stop taking TAFINLAR unless your doctor tells you to stop taking TAFINLAR.

Stopping your treatment with TAFINLAR 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.

While you are using TAFINLAR

Things you must do

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

Tell any other doctors, dentists, healthcare providers, or nurses 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 the medicine is working and to prevent unwanted side effects).

Your doctor will also perform routine medical examinations during treatment and after stopping treatment with TAFINLAR, to look for any possible skin malignancies that could have developed during treatment.

Your eyesight should be examined during therapy with TAFINLAR by a specialist eye doctor.

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.

In case you notice unexplained severe upper stomach pain you might be examined to find out whether you have an inflamed pancreas (pancreatitis). If an inflamed pancreas is confirmed you will have regular blood checks while taking TAFINLAR.

Signs you may need to look out for

Some people taking TAFINLAR develop other conditions, which can be serious.

If you are elderly, you may experience more severe side effects. In clinical trials, patients 65 years and older had more side effects which resulted in changes to their dose due to a higher frequency of severe side effects. Your doctor is aware of this.

While you are taking TAFINLAR, you need to know about the following important signs and symptoms to look out for.

- **FEVER (High temperature)**

  Taking TAFINLAR may cause high fever. High fever can also occur more often when you take TAFINLAR capsules together with MEKINIST tablet.

  Signs and symptoms of a fever may include:

  – Temperature of 38.0°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 38.0°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 TAFINLAR or TAFINLAR and MEKINIST 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 TAFINLAR and MEKINIST permanently.

- **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]).

- **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 while on treatment 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.

Things you must not do

Do NOT take TAFINLAR with food.

You must take it on an empty stomach.

Do NOT take TAFINLAR to treat any other conditions unless your doctor tells you to.

This medicine has been prescribed for only you.

Do NOT take the morning and evening doses of TAFINLAR at the same time.

TAFINLAR is dosed about every twelve (12) hours.

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 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 TAFINLAR affects you.
- Drinking alcohol while you are taking this medicine.

Side effects

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

Like all medicines, TAFINLAR 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 TAFINLAR alone

Stop taking this medicine and tell your doctor, healthcare provider, pharmacist or nurse, or get medical help immediately if you experience any of the following serious side effects (either for the first time or if they get worse):

- Abnormal growth of cancerous cells on the skin (signs of cutaneous squamous cell carcinoma (cuSCC) including SCC of the skin, SCC in situ (Bowen's disease, keratoacanthoma)
- Painful red eye (may be a sign of a disease of the eye called uveitis)
- Skin sore or reddish bump that bleeds or does not heal, a change in size or colour of a mole, or a new skin lesion (signs of new primary melanoma)
- Severe upper stomach pain or strong abdominal pain as this could be a sign of an inflamed pancreas
- 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 a hypersensitivity reaction)
- Severely decreased urine output. (sign of acute renal failure)
- High or low urine output, drowsiness, confusion, nausea as a sign of an inflamed kidney (tubulointerstitial nephritis).

Very common side effects when taking TAFINLAR alone

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

- Vomiting
- Unusual hair loss or thinning (alopecia)
- Thickening of the outer layers of the skin (hyperkeratosis)
- Skin effects such as rash, wart-like growths (papilloma)
- Skin effects such as rash, wart-like growths, or redness and/or swelling of the palms, fingers and soles of the feet, and, occasionally, elsewhere, which may be occur with a tingling sensation and burning pain (palmar-plantar erythrodysaesthesia syndrome)
- An irritated area of skin with changed colour, appearance, or texture (rash)
- Feeling like you want to vomit (nausea)
- Lack of energy
- Joint pain (arthralgia)
- Muscle pain (myalgia)
- Pain in the hands or feet (pain in the extremity)
- Headache
- Frequent loose or liquid bowel movements (diarrhoea)
- Reduced desire to eat (decreased appetite)
- Cough
- Feelings of coldness (chills)
- An increase in normal body temperature, or fever (pyrexia)
- Feeling weak (asthenia).

Common side effects when taking TAFINLAR alone

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

- Skin effects including:
  - "Sun spots" (rough scaly patches of skin that develop on sun-exposed areas of skin) (actinic keratosis)
  - Brown or yellowish thickening of the skin, or harmless “wart-like” skin growths (seborrhoeic keratosis)
  - Skin tags (soft, skin-coloured growths that hang from the surface of the skin on a thin piece of tissue or "stalk") (achrochordon)
  - Dry skin

  - Redness of the skin (erythema)
  - Itchy skin (an irritating feeling that makes you want to scratch an area of skin)
  - Skin lesions (parts of the skin that have an abnormal growth or appearance compared to the skin around it).
- Excessive thirst, high urine output, dark urine, increased appetite with weight loss, dry flushed skin, irritability, as signs of high level of sugar (glucose) in the blood (signs of hyperglycaemia)
- Tiredness, chills, sore throat, joint or muscles aching (Influenza-like illness)
- Infrequent or difficult emptying of the bowels (constipation)
- Sore throat, swelling of the nasal passages, and runny nose (nasopharyngitis)
- Increased sensitivity of the skin to sun (photosensitivity increased).
- Problems with the nerves that can produce pain, loss of sensation or tingling in hands and feet/muscle weakness (known as peripheral neuropathy)

Common side effects that can show up in test results

Some side effects may not give you any symptoms and can only be found when blood tests are done. These side effects are common:

- Low phosphorus in the blood (hypophosphataemia)
- High blood sugar (glucose) level (hyperglycaemia).

Uncommon side effects when taking TAFINLAR alone

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

- Tender or painful bumps below the surface of the skin (panniculitis).

Additional possible serious side effects when taking TAFINLAR together with MEKINIST

Refer to the MEKINIST Consumer Medicine Information for possible side effects and important signs and symptoms to look out for, such as heart problems, eye problems and rash.

Stop taking the combination of MEKINIST and TAFINLAR and tell your doctor immediately if you experience any of the following serious side effects:

- High temperature (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 or leukopenia). In some cases, low blood pressure and dizziness may occur with the fever.
- Headaches, dizziness, or weakness, coughing up blood or blood clots, vomit that contains blood or that looks like "coffee grounds", bleeding from the nose, or red or black stools (signs of haemorrhage)
- Generalized swelling (oedema includes generalized and peripheral oedema).
- Fever, sore throat or mouth ulcers due to infections (signs of leukopenia)
- Tiredness, confusion, muscle twitching, convulsions (hyponatremia)
- 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 bodySpontaneous bleeding or bruising (signs of thrombocytopenia)
- Thirst, low urine output, weight loss, dry flushed skin, irritability as signs of low level of fluids in the body (signs of dehydration)
- Loss of vision (sign of visual impairment)
- Sensation of flashing light, loss of vision (signs of retinal detachment)
- Slow heart-beat (sign of bradycardia)
- Acute severe upper stomach pain (sign of acute pancreatitis)
- Severely decreased urine output (sign of renal failure)
- High or low urine output, drowsiness, confusion, nausea as a sign of an inflamed kidney (tubulointerstitial nephritis)
- Abnormal breakdown of muscle causing pain, fever, red-brown urine (signs of rhabdomyolysis)
- Swelling in the eye by fluid leakage causing a blurred vision (signs of chorioretinopathy).
- Fatigue, feeling full or bloated, heart palpitations, loss of appetite, nausea, reduced ability to exercise, shortness of breath, swelling as signs of changes how the heart pumps (signs of left ventricular dysfunction)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs as signs of heart muscle not pumping blood as well as it should (signs of cardiac failure)
- Cough, difficult or painful breathing, wheezing, pain in chest when breathing, fever (signs of pneumonitis)
- Inflammation of the kidney (nephritis)
- Severe stomach pain, chills, fever, nausea and vomiting as signs of a hole forming all the way through the stomach, large

bowel or small intestine (signs of gastrointestinal perforation)

- Cramping diarrhoea with or without blood in stool, abdominal pain as signs of an inflammation of the inner lining of the colon (colitis)
- Fever, swollen glands, bruising or skin rash at the same time
- 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 possible side effects when TAFINLAR is taken with MEKINIST

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

- Sore throat and runny nose (nasopharyngitis)
- Urinary tract infection
- Swelling of the hands, ankles or feet (oedema peripheral)
- Stomach ache (abdominal pain)
- Rash, dry skin, itching, acne-like problems (dermatitis acneiform)
- Dry skin
- Skin itching (pruritus)
- Thickening of the outer layers of the skin (hyperkeratosis including also actinic keratosis, (thick scaly crusty skin), seborrhoeic keratosis (waxy, "pasted-on-the-skin" skin growths) and keratosis pilaris (rough, slightly red bumps on light skin and brown bumps on darker skin))
- Headaches, dizziness as signs of high blood pressure (hypertension)
- Dizziness
- Headache
- Constipation
- Skin reddening (erythema)
- Muscle spasms
- Dizziness, light-headedness (hypotension)
- Feeling weak, sick and tired (asthenia including malaise and fatigue)
- Tiredness, fatigue, pale skin (anaemia)
- Dry mouth
- Tiredness, chills, sore throat, joint or muscles aching (Influenza-like illness)
- Excessive thirst, high urine output, dark urine, increased appetite with weight loss, dry flushed skin, irritability, as signs of high level of sugar (glucose) in the blood (hyperglycaemia).

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

- Low levels of red blood cells (anaemia)
- Abnormal blood test results related to the bone or liver.

Common side effects (in combination with MEKINIST)

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

- Inflammation of the:
  - skin caused by an infection (cellulitis)
  - hair follicles that causes itching (folliculitis)
- Nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles (paronychia)
- Skin rash with pus-filled blister (rash pustular)
- Eyesight problems (blurred vision)
- Tiredness, chest discomfort, light headedness pain, palpitations (ejection fraction decreased)
- Hard and painful swelling in the arms, legs, or other part of the body (lymphoedema)
- Shortness of breath, laboured breathing (dyspnoea)
- A sore or inflammation inside of the mouth, including on the inner cheeks, gums, inside of the lips, or on the tongue (stomatitis)
- Night Sweats
- Excessive sweating (hyperhidrosis)
- Skin cracks or tears in the skin (Skin fissures)
- Tender or painful bumps below the surface of the skin (panniculitis)
- Swelling of face (face oedema)
- Pain, mouth sores, redness and swelling of airways or food pipe (mucosal inflammation)
- Problems with the nerves that can produce pain, loss of sensation or tingling in hands and feet/muscle weakness (known as peripheral neuropathy)
- Irregular heartbeat (atrioventricular block or bundle branch block)

Common side effects that may show up in your blood test results:

- Increase in some other substances produced by the liver
- Abnormal kidney function results as a sign of impaired muscle health.

Uncommon Side effects (in combination with MEKINIST)

Tell your doctor or pharmacist if you notice any of the following (that may affect less than 1 in 100 people):

- Swelling of the eyelids and swelling around the eyes (periorbital oedema)
- Cough, difficulty breathing, painful breathing (interstitial lung disease).
- Inflammatory disease mainly affecting the skin, lungs and eyes (sarcoidosis)
- Inflammation of the nerves which can result in pain, numbness, muscle weakness and paralysis of the arms and legs (Guillain-Barré syndrome)

Frequency unknown when taking TAFINLAR with MEKINIST

- 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 or nurse if you notice anything that is making you feel unwell.

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

After using TAFINLAR

Storage

Keep TAFINLAR capsules in the bottle until it is time to take them. Do not remove the desiccant.

If you take the capsules out of the pack/bottle without taking them, they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 30°C.

Do not store TAFINLAR or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot see or reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Dispose of medicines safely by returning TAFINLAR to your pharmacist for disposal when your doctor tells you to stop taking this medicine.

Do not throw TAFINLAR 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.

Product description

What TAFINLAR looks like

TAFINLAR capsules are available in plastic bottles containing 120 capsules. The bottle has a child resistant closure.

50 mg capsules

TAFINLAR 50 mg capsules are opaque, hard capsules composed of a dark red body and dark red cap containing a white to slightly coloured solid. The capsule shells are imprinted with GS TEW and 50 mg.

75 mg capsules

TAFINLAR 75 mg capsules are opaque, hard capsules composed of a dark pink body and dark pink cap containing a white to slightly coloured solid. The capsule shells are imprinted with GS LHF and 75 mg.

Ingredients

Each TAFINLAR capsule contains 50 or 75 mg of dabrafenib (as mesilate) as the active ingredient.

Each capsule also contains the following excipients:

- cellulose - microcrystalline (E460)
- magnesium stearate (E572)
- silica - colloidal anhydrous
- iron oxide red E172)
- titanium dioxide (E171)
- hypromellose (E464)
- iron oxide black (E464)
- shellac
- butan-1-ol
- isopropyl alcohol
- propylene glycol (E1520)
- ammonium hydroxide (E527)

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

Supplier

TAFINLAR is supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102 Newmarket

Auckland 1149

Telephone 0800 354 335

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