

# TAFINLAR®

dabrafenib (as mesilate) capsule

## Consumer Medicine Information

### What is in this leaflet

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.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 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

The active substance in TAFINLAR is dabrafenib. It belongs to a group of medicines called "Selective BRAF-inhibitors". TAFINLAR is a medicine used to treat people with

melanoma (a form of skin cancer) that has spread to other parts of the body or cannot be removed by surgery.

TAFINLAR can only be used to treat melanomas with a change (mutation) in a gene called "BRAF". This mutation may have caused the cancer to develop. TAFINLAR targets proteins made from this mutated gene and slows down or stops the development of your cancer.

TAFINLAR can be used by itself or in combination with another medicine called MEKINIST (containing trametinib). Your doctor may decide to treat your cancer with TAFINLAR alone or in combination with MEKINIST.

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

**Ask your doctor, pharmacist, or healthcare provider if you have any questions about 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. The safety and effects of TAFINLAR in people younger than 18 years old are not known.

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

It is not addictive.

### Before you take TAFINLAR

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

*When you must not take it*

**Do not take TAFINLAR if you have an allergy to:**

- Dabrafenib mesilate (active ingredient), or
- 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.

*Before you start to take it*

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

**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.
- Diabetes or high levels of sugar in your blood

If you are taking the combination of TAFINLAR and MEKINIST, your doctor, pharmacist, or healthcare

provider also needs to know if you have:

- 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, as the active ingredient(s) can harm an unborn baby.

**Tell your doctor, pharmacist or healthcare provider if you are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits with you.

**If you are a woman who could become pregnant, you must use reliable birth control (contraception) during treatment with TAFINLAR and for:**

- 28 days after you stop taking it **OR**
- at least 4 months following the last dose of MEKINIST (when taken in combination with TAFINLAR).

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

**You need to use another reliable method of birth control, such as**

**condoms, so you don't become pregnant while you are taking TAFINLAR. Ask your doctor or healthcare provider for advice.**

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

Men who are taking TAFINLAR may have a reduced sperm count while they are taking it. Their 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.**

### *Breast-feeding*

**Tell your doctor, pharmacist, or healthcare provider if you are breast feeding or planning to breast feed.**

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

TAFINLAR is not recommended while breast feeding.

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, pharmacist, or healthcare provider if you are taking 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 thin blood and prevent clots;
- Some medicines used 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 omeprazole) or antacids;
- Some medicines to lower fats (lipids) in the blood stream, such as gemfibrozil;
- Some anti-inflammatory medicines such as dexamethasone;
- Some medicines to treat HIV, such as ritonavir, saquinavir and atazanavir;
- Some medicines to treat seizures (epilepsy), such as phenytoin, phenobarbital, or carbamazepine;
- Some anti-depressant medicines such as nefazodone and the herbal medicine St John's wort (*Hypericum perforatum*).

**Tell your doctor, pharmacist, or healthcare provider if you are taking any of these (or if you are not sure).**

Your doctor may decide to adjust your dose.

**Keep a list of medicines you take, so that 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.

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## **How to take TAFINLAR**

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

They may differ from the information contained in this leaflet.

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

### *When to take it*

#### **Take TAFINLAR:**

- Twice a day, about 12 hours apart from the previous dose
- At about the same time each day.

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

**If taking TAFINLAR AFTER eating a meal or snack, wait at least 2 hours before taking it.**

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

### *How much to take*

The usual dose of TAFINLAR is **150 mg taken on an empty stomach as:**

- Two 75 mg capsules  
or
- Three 50 mg capsules

**You must take 2 TAFINLAR doses each day.**

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

The usual total daily dose is 300 mg. Depending on how you respond to TAFINLAR, your doctor may prescribe you a lower dose or interrupt temporarily the treatment.

**Don't take 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.

### *How to take it*

**Take TAFINLAR on an empty stomach.**

**Swallow the capsule whole, with a full glass of water. Take the**

**capsules, one after the other, unless your doctor has advised a lower dose.**

If you get side effects, your doctor may decide that you should take a lesser dose.

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

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## When taking TAFINLAR in combination with MEKINIST

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**Take TAFINLAR in combination with MEKINIST exactly as your doctor, pharmacist, or healthcare provider tells you.**

**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 MORE THAN ONE DOSE OF MEKINIST PER DAY.**

**Do not change your dose or stop TAFINLAR in combination with MEKINIST unless your doctor tells you.**

### *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 unless your doctor advises you to.**

**If you have any further questions about how long to take TAFINLAR, ask your doctor.**

### *If you forget to take it*

**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.**

**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, healthcare provider, or pharmacist for some hints.**

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## If you take too much (overdose)

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**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, 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 medications with you.**

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## While you are taking TAFINLAR

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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 TAFINLAR.**

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

Your doctor might perform medical examinations during treatment and after stopping treatment with TAFINLAR to look for possible malignancies that could have developed during treatment.

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

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

## *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 older than 65 years had more side effects that resulted in amendments to their dose and had 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.

### **BLEEDING PROBLEMS**

Taking TAFINLAR alone (or in combination with MEKINIST) can cause serious bleeding problems, especially in the brain or stomach, that may lead to death.

**Tell your doctor or healthcare provider and get medical help immediately if you have any unusual signs of bleeding while you are taking this medicine.**

### **FEVER**

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

**Tell your doctor or healthcare provider immediately if you get a fever while you are taking TAFINLAR.**

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

In some cases, people with fever may develop low blood pressure and dizziness. If the fever is severe, your doctor may recommend that you stop taking TAFINLAR while they treat the fever with other medicines. Once the fever is controlled, your doctor may recommend that you start taking TAFINLAR again.

### **CHANGES TO YOUR SKIN BEFORE, DURING AND AFTER TREATMENT**

**Check your skin regularly whilst taking TAFINLAR and tell your doctor immediately if you notice any changes to your skin while taking this medicine.**

Some patients taking TAFINLAR may develop a different type of skin cancer called cutaneous squamous cell carcinoma (cuSCC). Usually, this lesion remains local and can be removed with surgery and people can continue TAFINLAR treatment.

**Tell your doctor immediately if you notice any changes to your skin while taking this medicine**

Your doctor will check your skin before you start taking TAFINLAR, regularly while you are taking this medicine, and for some months after you stop taking it.

### **EYE PROBLEMS**

TAFINLAR can cause an eye problem called uveitis which could damage your vision if it is not

treated. Uveitis may develop rapidly.

**Tell your doctor immediately if you get any vision changes during your treatment.**

If symptoms develop, your doctor may arrange for you to see an eye specialist for a complete eye examination.

### **STRONG ABDOMINAL PAIN**

Taking TAFINLAR may cause inflammation of the pancreas.

**Tell your doctor immediately if you notice strong abdominal pain.**

### **HIGH BLOOD SUGAR LEVELS**

Patients with a history of diabetes required more intensive therapy to reduce their blood sugar while taking TAFINLAR.

**Tell your doctor if you notice symptoms of excessive thirst or increase in the volume or frequency of urination.**

## *Things you must not do*

**Do NOT take TAFINLAR with food.**

You must take it on an empty stomach.

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

TAFINLAR is dosed about every twelve (12) hours.

**Do NOT take TAFINLAR to treat any other conditions 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 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.

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## Side effects

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**Tell your doctor, healthcare provider, 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 side effects when taking TAFINLAR alone*

### SERIOUS SIDE EFFECTS

**Stop taking TAFINLAR and tell your doctor, healthcare provider, or pharmacist or get medical help immediately if you experience any serious side effects.**

- 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)
- New wart, skin sore or reddish bump that bleeds or does not heal, a new skin lesion, or a change in size or colour of a mole (signs of a new primary melanoma)
- Severe upper stomach pain (sign of pancreatitis)
- Painful red eye (sign of uveitis)
- 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)

*Other possible side effects when TAFINLAR is taken*

### VERY COMMON SIDE EFFECTS

**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)
  - rash, wart-like growths, or redness and/or swelling and possibly peeling of the palms, fingers and soles of the feet which may be accompanied by tingling sensation and burning pain (palmar-plantar erythrodysesthesia syndrome)
- Rash
- Nausea
- Lack of energy
- Joint pain (arthralgia)
- Muscle pain (myalgia)
- Pain in the hands or feet (pain in extremity)
- Headache
- Diarrhoea
- Decreased appetite
- Cough
- Chills
- Fever (pyrexia)
- Feeling weak (asthenia)

### COMMON SIDE EFFECTS

**Tell your doctor or pharmacist if you notice any of the following**

**(that may affect up to 1 in 10 people):**

- Rough scaly patches of skin (actinic keratosis)
- Brown or yellowish to red thickening of the skin (seborrhoeic keratosis)
- Skin tags (acrochordon)
- Dry skin
- Redness of the skin (erythema)
- Itching (pruritis)
- Skin lesions
- 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)
- Constipation
- Sore throat and runny nose (nasopharyngitis)
- Increased sensitivity of the skin to sun (photosensitivity increased).

### Common side effects that can show up in blood tests

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, which shows up in blood tests (hypophosphataemia)
- High blood sugar (glucose).

### UNCOMMON SIDE EFFECTS

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

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

*Additional possible 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.**

When you take TAFINLAR and MEKINIST together, you may get:

- Any of the side effects given in the lists above, although the frequency may change (increase or decrease);
- A persistent high temperature (fever); in some cases, low blood pressure and dizziness with fever.

**Tell your doctor as soon as possible if you get a fever while taking TAFINLAR in combination with MEKINIST.**

### **SERIOUS SIDE EFFECTS**

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

- 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)
- 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)
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration (signs of pulmonary embolism)
- Spontaneous 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)
- 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)
- Swelling in the eye by fluid leakage causing a blurred vision (signs of chorioretinopathy)
- Cough, difficult or painful breathing, wheezing, pain in chest when breathing, fever (signs of pneumonitis)
- Abnormal breakdown of muscle causing pain, fever, red-brown urine (signs of rhabdomyolysis)
- Inflammation of the kidney (nephritis)
- Swelling in the eye by fluid leakage causing a blurred vision (signs of chorioretinopathy)
- 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)
- 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
- Tiredness, confusion, muscle twitching, convulsions (hyponatraemia)
- Skin reddening (erythema)
- Muscle spasms
- Dizziness, light-headedness (hypotension)
- Feeling weak, sick and tired (asthenia including malaise and fatigue).

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

- Related to the liver showing high levels of any of the following enzymes:
  - blood alkaline phosphatase (AP) increased (bone function)
  - alanine aminotransferase (ALT) and/or
  - aspartate aminotransferase (AST) increased (liver function).

### **COMMON SIDE EFFECTS (IN COMBINATION WITH MEKINIST)**

**Tell your doctor or pharmacist if you notice any of the following**

*Other possible side effects when TAFINLAR is taken with MEKINIST*

### **VERY COMMON SIDE EFFECTS (IN COMBINATION WITH MEKINIST)**

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

**(that may affect up to 1 in 10 people):**

- Inflammation of the skin caused by an infection (cellulitis)
- Inflammation of hair follicles that causes itching (folliculitis)
- Nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles (paronychia)
- Rash with pus-filled blister (rash pustular)
- Tiredness, fatigue, pale skin (anaemia)
- 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)
- Mouth sores with gum inflammation (stomatitis)
- Dry mouth
- Night sweats
- Excessive sweating (hyperhidrosis)
- 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)
- Decreased urine output.

**Common side effects that may show up in abnormal test results:**

- Decreased levels of red blood cells (anaemia)
- Increased levels of Gamma-glutamyl transferase (GGT) (liver function).

**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 around the eye (periorbital oedema)
- Cough, difficulty breathing, painful breathing (interstitial lung disease).

**Tell your doctor, pharmacist, or healthcare provider if you notice anything not listed that is making you feel unwell.**

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

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## After using TAFINLAR

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### *Storage*

**Keep TAFINLAR capsules in the bottle until it is time to take them.**

If you take the capsules out of the pack/bottle 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 reach it.**

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

### *Disposal*

**If the packaging is torn or shows signs of tampering when you receive 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 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.

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## Product description

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### *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 printed 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 printed with GS LHF and 75 mg.

### *Ingredients*

Each capsule contains 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 (E172)
- Shellac
- Butan-1-ol
- Isopropyl alcohol
- Propylene glycol (E1520)
- Ammonium hydroxide (E527)

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

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## Supplier

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TAFINLAR is supplied by:

**Novartis Pharmaceuticals**

**Australia Pty Limited**

ABN 18 004 244 160

54 Waterloo Road, Macquarie Park

NSW 2113 Australia

Telephone 1 800 671 203

[www.novartis.com.au](http://www.novartis.com.au)

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