NOVARTIS

RAFINLAR (Dabrafenib)

50 and 75 mg capsules

Patient Information Leaflet

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SCHEDULING STATUS: **S4**

RAFINLAR 50 mg capsules

RAFINLAR 75 mg capsules

dabrafenib mesylate

Read all of this leaflet carefully before you start taking RAFINLAR

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.**
- **RAFINLAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

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

1. What RAFINLAR is and what it is used for

The active ingredient in RAFINLAR 50 mg capsules contains 59.25 mg dabrafenib mesylate equivalent to 50 mg free base.

The active ingredient in RAFINLAR 75 mg capsules contains 88.88 mg dabrafenib mesylate equivalent to 75 mg free base.

RAFINLAR belongs to a group of medicines called “selective BRAF inhibitors”.
RAFINLAR is a medicine used in combination with trametinib 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.

RAFINLAR is a medicine that can be 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.

RAFINLAR is a medicine that is also used in combination with trametinib for the adjuvant treatment of adult patients with Stage III melanoma (a form of skin cancer) with BRAF V600 mutation, following complete resection.

RAFINLAR is a medicine that is also used in combination with trametinib to treat people with a type of lung cancer called non-small cell lung cancer (NSCLC) adenocarcinoma.

RAFINLAR is used in combination with trametinib for children of 6 years and older that are weighing at least 26 kg with low-grade glioma (LGG).

RAFINLAR is used in combination with trametinib in both adults and children from 6 year of age weighing at least 26 kg for the treatment of solid tumours (type of cancer) that have advanced after previous treatment and there are no adequate alternatives available.

Your doctor may decide to treat your melanoma with a combination of RAFINLAR and trametinib.
If you are taking these two medicines together, read the trametinib leaflet as well as this leaflet.

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

2. What you need to know before you take RAFINLAR

Your doctor may decide to treat your melanoma with a combination of RAFINLAR and trametinib.

If you are taking these two medicines together, read the trametinib leaflet as well as this leaflet.

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

Do not take RAFINLAR

- If you are hypersensitive (allergic) to dabrafenib or any of the other ingredients of RAFINLAR (listed in section 6).
- If you are pregnant or breastfeeding your baby.

If any of these apply to you, do not take RAFINLAR and tell your doctor.

Warnings and precautions

Take special care with RAFINLAR.

If any of the following apply to you, tell your doctor or pharmacist or healthcare provider before taking RAFINLAR:

- If you have any liver problems. Your doctor may take blood samples to monitor your liver function while you are taking RAFINLAR.
- If you have or have ever had any kidney problems.
- If you develop a fever, or if you feel a fever coming on. Fever may be accompanied by severe chills, dehydration and low blood pressure. This can occur more often when you take RAFINLAR together with trametinib.
- If you experience high fever, headaches, dizziness, or weakness, coughing up of blood or blood clots, vomit containing blood or that looks like “coffee grounds”, bleeding from nose, red or black stools that look like tar. These may be signs of severe bleeding.
- If you notice any changes in your skin, such as new wart, skin sore or reddish bump that bleeds or does not heal, change in size or colour of a mole these may be signs of a different skin cancer named cutaneous squamous cell carcinoma. These lesions are usually removed by surgery and people can continue treatment.

- If you notice that new melanomas have appeared.
- If you get severe upper stomach pain. This may be a sign of an inflamed pancreas.
- If you get a painful red eye. This may be a sign of a disease of the eye named uveitis.
- If you have a disease of excessive immune activation (Haemophagocytic lymphohistiocytosis (HLH).
- If you have a condition called tumour lysis syndrome (TLS), characterised by nausea, vomiting, shortness of breath, irregular heartbeat, clouding of urine, lethargy and joint discomfort.

Monitoring during your treatment with RAFINLAR

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 doctor will check your skin before you start taking RAFINLAR, then check it again every 2 months while you are taking RAFINLAR and every 2 or 3 months for 6 months after you stop taking RAFINLAR, to look for any new skin cancers.

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

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

Older people (65 years or above)
You can use RAFINLAR if you are aged 65 years or above at the same dose as for younger adults.

Children and adolescents (below 18 years)

The safety and efficacy of RAFINLAR have not been established in children and adolescents younger than 18 years).

Other medicines and RAFINLAR

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Some medicines may affect how RAFINLAR works or make it more likely that you'll have side effects.

RAFINLAR can also affect how some other medicines work. These include:

- birth control using hormones such as pills, injections, or patches
- warfarin, to thin the blood
- medicines to treat fungal infections, such as ketoconazole
- some antibiotic medicines, such as clarithromycin or rifampin
- medicines to treat inflammations such as dexamethasone
- medicines to lower fats (lipids) in the blood stream, such as gemfibrozil
- medicines that reduce stomach acid, such as proton pump inhibitors, H2 antagonists or antacids
- some medicines to treat HIV, such as ritonavir
- medicines to treat seizures, such as phenytoin, phenobarbital, or carbamazepine
- the anti-depressant medicine nefazodone
- the herbal product St John's wort.

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. Ask your doctor, nurse or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

RAFINLAR with food and drink

It is important to take RAFINLAR on an empty stomach, because food may affect the way the medicine is absorbed into your body. Take RAFINLAR with a full glass of water.

You must take RAFINLAR at least 1 hour before a meal or 2 hours after a meal, so:

- after taking RAFINLAR wait at least 1 hour before eating
- or, after eating, wait at least 2 hours before taking RAFINLAR.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking RAFINLAR.

You must not take RAFINLAR if you are pregnant.

You must not take RAFINLAR if you are breastfeeding.

Women who might get pregnant (women of child-bearing age)

Women who might get pregnant must use highly effective contraception while taking RAFINLAR and for four weeks after stopping treatment with RAFINLAR.

RAFINLAR may decrease the efficacy of hormonal contraceptives and an alternate method of contraception, such as barrier methods, should be used.

Male patients must use a condom during intercourse and not father a child during therapy and for 4 months after stopping treatment with RAFINLAR.

If you are a man taking RAFINLAR

Men who are taking RAFINLAR may have a reduced sperm count while they are taking it. Their sperm count may not return to normal levels after they stop taking RAFINLAR.

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

Driving and using machinery

Do not drive or use machines until you know if RAFINLAR affects your performance.

It is not always possible to predict to what extent RAFINLAR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RAFINLAR affects them.

3. How to take RAFINLAR

Do not share medicines prescribed for you with any other person.

Always take RAFINLAR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose prescribed by your doctor.

RAFINLAR is for oral use only.

The usual dose of RAFINLAR is 150 mg (two 75 mg capsules) twice a day.

Your doctor will tell you how long your treatment with RAFINLAR will last. Your doctor may decide that you should take a lower dose if you get side effects.

Don’t take any more RAFINLAR than your doctor has recommended.

How to take RAFINLAR

- Swallow the RAFINLAR capsules whole, with water, one after the other.
- Take RAFINLAR twice a day, on an empty stomach (at least 1 hour before a meal or 2 hours after a meal), so:
- after taking RAFINLAR, wait **at least 1 hour** before eating
- or, after eating, wait **at least 2 hours** before taking RAFINLAR.
- Take RAFINLAR at about the same time each day.

Taking RAFINLAR together with trametinib

- Swallow the RAFINLAR capsules and the trametinib tablet with a full glass of water.

- Take RAFINLAR in combination with trametinib exactly as your doctor or pharmacist tells you. Do not change your dose unless your healthcare provider tells you.
- Take the first dose of RAFINLAR in the morning and take the second dose of RAFINLAR separately in the evening approximately 12 hours later.

When RAFINLAR and trametinib are taken in combination take the once daily dose of trametinib at the same time each day with either the morning or the evening dose of RAFINLAR.

- Do not take more than one dose of trametinib a day and do not take the morning and evening doses of RAFINLAR at the same time.

Continue taking RAFINLAR every day for as long as your doctor tells you. This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect. If you have questions about how long to take RAFINLAR, talk to your doctor, nurse or pharmacist.

If you take more RAFINLAR than you should

If you take too many tablets of RAFINLAR, contact your doctor, nurse or pharmacist for advice. If neither is available, contact the nearest hospital or poison centre. If possible, show them the RAFINLAR pack.

If you forget to take RAFINLAR

If the missed dose is less than 6 hours late, take it as soon as you remember. If the missed dose is more than 6 hours late, skip that dose and take your next dose at the usual time. Then carry on taking RAFINLAR at regular times as usual.

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

If you stop taking RAFINLAR

Take RAFINLAR for as long as your doctor recommends. Don’t stop unless your doctor advises you to.

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

4. Possible side effects

RAFINLAR can have side effects.

Not all side effects reported for RAFINLAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RAFINLAR, please consult your health care provider for advice.

Some symptoms need immediate medical attention.

If any of the following happens, stop taking RAFINLAR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- New wart, skin sore or reddish bump that bleeds or does not heal, change in size or colour of a mole (signs of 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 hypersensitivity reaction)
- Severely decreased urine output (sign of acute renal failure)

These are all very serious side effects. If you have them, you may have had a serious reaction to RAFINLAR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Vomiting
- Unusual hair loss or thinning

- Thickening of the outer layers of the skin
- Skin effects such as rash, wart-like growths, or redness and swelling of the palms, fingers and soles of the feet
- Nausea
- Lack of energy
- Joint pain, muscle pain, or pain in the hands or feet
- Headache
- Diarrhoea
- Decreased appetite
- Cough
- Chills
- Fever
- Feeling weak
- Skin effects including rough scaly patches of skin, brown or yellowish thickening of the skin, skin tags, dry skin or redness of the skin
- Low phosphorus in the blood
- Itching
- Thirst, low urine output, dark urine, dry flushed skin, irritability (high sugar (glucose) in the blood)
- Tiredness, chills, sore throat, joint or muscles aching (flu-like illness)
- Constipation
- Sore throat and runny nose (nasopharyngitis)
- Fever, sore throat or mouth ulcers due to infections (signs of neutropenia or leukopenia)
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration (signs of pulmonary embolism)
- Headaches, dizziness, or weakness, coughing up of blood or blood clots, vomit containing blood or that looks like “coffee grounds”, bleeding from nose, red or black stools (signs of haemorrhage)
- Spontaneous bleeding or bruising (signs of thrombocytopenia)

- Thirst, low urine output, weight loss, dry flushed skin, irritability (signs of low level of fluids in the body)
- Loss of vision (sign of visual impairment)
- Blurred vision (signs of chorioretinopathy)
- Sensation of flashing light, loss of vision (signs of retinal detachment)
- Fatigue, feeling full or bloated, heart palpitations, loss of appetite, nausea, reduced ability to exercise, shortness of breath, swelling (signs of left ventricular dysfunction)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- Slow heartbeat (sign of bradycardia)
- 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)
- Nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching (signs of hypercalcemia)
- Urinary tract infection
- Swelling of the hands or feet
- Stomachache
- Rash, dry skin, itching, acne like problem
- Headache, dizziness (high blood pressure)
- Dizziness
- Weight decreased
- During RAFINLAR treatment, you may also have side effects of abnormal blood test results, which can give your doctor information on the functioning of some parts of your body, for example:
    - High levels of the following enzymes: blood alkaline phosphatase increased (bone function), alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (liver function)
- Inflammation of the skin caused by infection (cellulitis)

- Inflammation of hair follicles that cause 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)
- Tiredness, confusion, muscle twitching, convulsions (hyponatraemia)
- Eyesight problems
- Tiredness, chest discomfort, light headedness pain, palpitations (ejection fraction decreased)
- Dizziness, light-headedness (hypotension)
- Short of breath, laboured breathing (dyspnoea)
- Mouth sores with gum inflammation (stomatitis)
- Dry mouth
- Thick scaly crusty skin (actinic keratosis)
- Night sweats
- Excessive sweating
- Skin fissures
- Tender or painful bumps below the surface of the skin (panniculitis)
- Muscle spasms
- Abnormal kidney blood test result (blood creatine phosphokinase increased)
- Swelling of the face
- Pain, mouth sores, redness and swelling of airways or food pipe (mucosal inflammation)
- Weight increase
- During RAFINLAR treatment, you may also have side effects of abnormal blood test results, which can give your doctor information on the functioning of some parts of your body, for example:
    - High levels of the following enzymes: Blood alkaline phosphatase increased (bone function), gamma-glutamyl transferase (GGT) increased (liver function)
- Swelling of the eyelids and swelling around the eye (periorbital oedema)

- Hard and painful swelling in the arms, legs, or other part of the body (lymphoedema)
- Cough, difficulty breathing, painful breathing (interstitial lung disease)
- Inflammatory disease mainly affecting the skin, lungs and eyes (sarcoidosis)
- Heart condition (atrioventricular block and bundle branch block) with the following signs and symptoms, light-headedness or dizziness, palpitations, fatigue, chest pain, shortness of breath and fainting spells
- Excessive immune activation (Haemophagocytic lymphohistiocytosis (HLH) characterised by fever, rash, confusion even seizures).
- Tumour lysis syndrome (TLS) characterised by nausea, vomiting, shortness of breath, irregular heartbeat, clouding of urine, lethargy and joint discomfort.
- Numbness and tingling feeling in the feet and hands (peripheral neuropathy).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of RAFINLAR.

5. How to store RAFINLAR

Store all medicines out of reach of children.

Store at or below 30 °C, protect from moisture.

Store in the original package.

6. Contents of the pack and other information

What RAFINLAR contains:

The active substance is dabrafenib. Each hard capsule contains dabrafenib mesylate equivalent

to 50 mg or 75 mg of dabrafenib.

The other ingredients are:

Hypromellose capsule: microcrystalline cellulose, magnesium stearate (vegetable source), colloidal silicon dioxide.

Shell composition: red iron oxide, titanium dioxide, hypromellose.

Monogramming: black iron oxide, shellac, ammonium hydroxide.

RAFINLAR does not contain sugar.

What RAFINLAR looks like and contents of the pack

RAFINLAR 50 mg

Opaque, size 2 capsules composed of a dark red body and dark red cap containing a white to slightly coloured solid. Capsule shells imprinted with GS TEW and 50 mg.

RAFINLAR 75 mg

Opaque, size 1 capsules composed of a dark pink body and dark pink cap containing a white to slightly coloured solid. Capsule shells imprinted with GS LHF and 75 mg.

RAFINLAR 50 mg and 75 mg capsules are packed in white HDPE bottles with white child resistant polypropylene closures inside an outer carton. This product is packaged with a silica desiccant.

Pack sizes: 28, 56 or 120 capsules per bottle.

Holder of Certificate of Registration

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