

Dabrafenib 50mg and 75mg Hard Capsules

What is in this leaflet

1. What Rafinlar is used for
2. How it works
3. Before you use Rafinlar
4. How to use Rafinlar
5. While you are using it
6. Side effects
7. Storage and Disposal of product
8. Product description
9. Manufacturer
10. Product Registration Holder
11. Date of Revision
12. Serial number

What Rafinlar is used for

RAFINLAR is a prescription medicine used:

- alone or in combination with a medicine called trametinib to treat a type of skin cancer called melanoma:
 - that has spread to other parts of the body or cannot be removed by surgery, **and**
 - that has a certain type of abnormal “BRAF” gene.
- in combination with trametinib, to help prevent melanoma that has a certain type of abnormal “BRAF” gene from coming back after the cancer has been removed by surgery.
- in combination with trametinib to treat a type of lung cancer called non-small cell lung cancer (NSCLC):
 - that has spread to other parts of the body, **and**
 - that has a certain type of abnormal “BRAF” gene.
- in combination with trametinib to treat solid tumors in adults and children 6 years and older:
 - that cannot be removed with surgery or have spread to other parts of the body, and that have gotten worse (progressed) and you have no satisfactory treatment options, **and**
 - that have a certain type of abnormal “BRAF” gene.

RAFINLAR is not for use in treating people with colorectal cancer or wild-type BRAF solid tumors.

Your healthcare provider will perform a test to make sure that RAFINLAR is right for you.

It is not known if RAFINLAR used in combination with trametinib is safe and effective in children younger than 1 year of age.

It is not known if RAFINLAR used alone is safe and effective in children.

How Rafinlar works

Melanoma, non-small cell lung cancer, solid tumors have a particular change (mutation) in a gene called BRAF. This mutation in the gene may have caused the cancer to develop. Your medicine targets proteins made from this changed (mutated) gene and slows down or stops the development of your cancer.

If you have any questions about how Rafinlar works or why this medicine has been prescribed for you, ask your doctor, pharmacist or healthcare provider.

Before you use Rafinlar

- Before you start to use it

Before you take or give RAFINLAR, tell your healthcare provider about all of your medical conditions, including if you:

- have had bleeding problems
- have heart problems
- have eye problems
- have liver or kidney problems
- have diabetes
- plan to have surgery, dental, or other medical procedures
- have a deficiency of the glucose-6-phosphate dehydrogenase (G6PD) enzyme
- are pregnant or plan to become pregnant. RAFINLAR can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will do a test to see if you are

pregnant before starting treatment with RAFINLAR.

- You should use effective birth control (contraception) during treatment with RAFINLAR and for 2 weeks after your last dose of RAFINLAR.
- Birth control methods that contain hormones (such as birth control pills, injections, or transdermal systems) may not work as well during treatment with RAFINLAR and you could become pregnant. You should use another effective method of birth control during treatment with RAFINLAR.
- Talk to your healthcare provider about birth control methods that may be right for you during this time.
- Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with RAFINLAR.

Males (including those who have had a vasectomy) with a female partner who is able to become pregnant:

- Use condoms during sexual intercourse during treatment with RAFINLAR and for at least 2 weeks after your last dose of RAFINLAR.
- are breastfeeding or plan to breastfeed. It is not known if RAFINLAR passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after your last dose of RAFINLAR. Talk to your healthcare provider about the best way to feed your baby during this time.

- Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Dabrafenib 50mg and 75mg Hard Capsules

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How to use Rafinlar

- Take or give RAFINLAR exactly as your healthcare provider tells you. Do not change your dose or stop RAFINLAR unless your healthcare provider tells you.
- Your healthcare provider may change your dose of RAFINLAR, temporarily stop, or completely stop your treatment with RAFINLAR if you develop certain side effects.

- How much to use

The usual dose of Rafinlar is 150 mg (two 75 mg capsules), twice a day. Depending on how you respond to Rafinlar, your doctor may prescribe you a lower dose or interrupt temporarily the treatment.

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

- When to use it

RAFINLAR capsules:

- Take RAFINLAR 2 times a day, at the same time each day, about 12 hours apart.
- Take RAFINLAR on an empty stomach (at least 1 hour before or 2 hours after a meal).
- Take RAFINLAR capsules whole. Do not open, crush, or break RAFINLAR capsules.
- If RAFINLAR capsules are prescribed for your child 6 years of age or older, your child's healthcare provider will adjust their dose as your child grows.
- Tell your healthcare provider if you or your child is not able to swallow RAFINLAR capsules whole.

- How long to use it

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.

- If you forget to use it

- If you miss a dose of RAFINLAR, take or give it as soon as you remember. **Do not take or give a missed dose of RAFINLAR if it is less than 6 hours before your next scheduled dose.** Just skip the missed dose and take or give the next dose of RAFINLAR at the regular time.
- If vomiting happens after taking or giving a dose of RAFINLAR, do not take or give an additional dose. Take or give the next dose of RAFINLAR at the regular time.

- If you use too much (overdose)

If you take too many capsules of Rafinlar, or if somebody else accidentally takes your medicine, contact a doctor or a hospital immediately for advice. If possible, show them the Rafinlar pack. Medical treatment may be necessary.

While you are using it

- Things you must not do

Do not use RAFINLAR for a condition for which it was not prescribed. Do not give RAFINLAR to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about RAFINLAR that is written for health professionals.

Side effects

RAFINLAR may cause serious side effects, including:

- **Risk of new cancers.** RAFINLAR, when used alone or with trametinib, may cause skin cancers, called cutaneous squamous cell carcinoma

(cuSCC), keratoacanthoma, basal cell carcinoma, or melanoma.

Talk with your healthcare provider about your risk for these cancers.

Check your skin and tell your healthcare provider right away about any skin changes, including:

- new wart
- skin sore or reddish bump that bleeds or does not heal
- change in size or color of a mole

Your healthcare provider should check your skin before treatment with RAFINLAR, every 2 months during treatment with RAFINLAR, and for up to 6 months after you stop taking RAFINLAR to look for any new skin cancers.

Your healthcare provider should also check for cancers that may not occur on the skin. Tell your healthcare provider about any new symptoms that develop during treatment with RAFINLAR.

- **bleeding problems.** RAFINLAR, when taken or given with trametinib, can cause serious bleeding problems, especially in your brain or stomach, that can lead to death. Call your healthcare provider and get medical help right away if you have any signs of bleeding, including:
 - headaches, dizziness, or feeling weak
 - cough up blood or blood clots
 - vomit blood or your vomit looks like "coffee grounds"
 - red or black stool that looks like tar
- **heart problems,** including heart failure. Your healthcare provider should check your heart function before and during treatment with RAFINLAR. Call your healthcare provider right away if you have

Dabrafenib 50mg and 75mg Hard Capsules

any of the following signs and symptoms of a heart problem:

- feeling like your heart is pounding, racing or beating irregularly
- shortness of breath
- swelling of your ankles or feet
- feeling lightheaded

- **eye problems.** RAFINLAR can cause severe eye problems that can lead to blindness. Call your healthcare provider right away if you get these symptoms of eye problems:

- blurred vision, loss of vision, or other vision changes
- see color dots
- halo (see blurred outline around objects)
- eye pain, swelling, or redness

- **fever.** Fever is common during treatment with RAFINLAR, but may also be serious. When taking RAFINLAR with trametinib, fever may happen more often or may be more severe. In some cases, chills or shaking chills, too much fluid loss (dehydration), low blood pressure, dizziness, or kidney problems may happen with the fever.

Call your healthcare provider right away if you get a fever during treatment with RAFINLAR.

Your healthcare provider may temporarily or permanently stop your treatment or change your dose of RAFINLAR with trametinib if you have fevers. Your healthcare provider will treat you as needed for your fever and any signs and symptoms of infection and should check your kidney function during and after you have had severe fever.

- **serious skin reactions.** Skin rash is a common side effect of

RAFINLAR. RAFINLAR can also cause other skin reactions. In some cases, these rashes and other skin reactions can be severe or serious and may need to be treated in a hospital or lead to death.

Tell your healthcare provider if you get a skin rash or acne that bothers you or worsens.

Tell your healthcare provider right away if you develop any new or worsening symptoms of a severe skin reaction, including:

- blisters or peeling of your skin
- mouth sores
- blisters on your lips, or around your mouth or eyes
- high fever or flu-like symptoms
- enlarged lymph nodes

- **increased blood sugar (hyperglycemia).** Some people may develop high blood sugar or worsening diabetes during treatment with RAFINLAR. If you are diabetic, your healthcare provider should check your blood sugar levels closely before and during treatment with RAFINLAR. Your diabetes medicine may need to be changed. Tell your healthcare provider if you have any of the following symptoms of severe high blood sugar:

- increased thirst
- urinating more often than normal, or urinating an increased amount of urine

- **RAFINLAR may cause healthy red blood cells to break down too early in people with G6PD deficiency.** This may lead to a type of anemia called hemolytic anemia where the body does not have enough healthy red blood cells. Tell your healthcare provider if you have any of the following signs or symptoms:
 - yellow skin (jaundice)

- weakness or dizziness
- shortness of breath

- **hemophagocytic lymphohistiocytosis (HLH).** RAFINLAR when taken or given with trametinib may increase the risk of a type of overactivity of the immune system (hemophagocytic lymphohistiocytosis) that can cause fever, swollen glands, bruising, or skin rash. If you experience a combination of these symptoms, call your healthcare provider right away.

The most common side effects of RAFINLAR when taken alone include:

- thickening of the outer layers of the skin
- headache
- fever
- joint aches
- warts
- hair loss
- redness, swelling, peeling, or tenderness of hands or feet

The most common side effects of RAFINLAR when taken with trametinib in people with melanoma that has spread to other parts of the body or cannot be removed by surgery include:

- fever
- rash
- headache
- chills
- joint aches
- cough

The most common side effects of RAFINLAR when taken with trametinib to help prevent melanoma from coming back after the cancer has been removed by surgery include:

- fever
- tiredness
- nausea
- headache
- rash
- chills
- diarrhea
- vomiting
- joint aches
- muscle aches

The most common side effects of RAFINLAR when taken with trametinib in people with NSCLC include:

Dabrafenib 50mg and 75mg Hard Capsules

- fever
- tiredness
- nausea
- vomiting
- diarrhea
- dry skin
- decreased appetite
- rash
- swelling of face, arms, and legs
- chills
- bleeding
- cough
- shortness of breath

The most common side effects of RAFINLAR when taken with trametinib in adults with solid tumors that cannot be removed by surgery or have spread to other parts of the body include:

- fever
- tiredness
- nausea
- rash
- chills
- headache
- bleeding
- cough
- vomiting
- constipation
- diarrhea
- muscle and joint aches
- swelling of your arms and legs

RAFINLAR may cause fertility problems in females. This could affect your ability to become pregnant. Talk to your healthcare provider if this is a concern for you.

RAFINLAR may cause lower sperm counts in males. This could affect the ability to father a child. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of RAFINLAR.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Rafinlar

- Storage

- Do not store above 30°C. Store in the original container. Do not remove the desiccant.

- Rafinlar must be kept out of the reach and sight of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Rafinlar is supplied as capsules of 50 mg and 75 mg.

- **50 mg capsules:** opaque, dark red capsules, and marked with 'GS TEW' and '50 mg'.
- **75 mg capsules:** opaque, dark pink capsules, and marked with 'GS LHF' and '75 mg'.

- Ingredients

- Active ingredient(s)

Dabrafenib

- Inactive ingredients

Hard capsule: microcrystalline cellulose (cellulose, microcrystalline), magnesium stearate (vegetable source), colloidal silicon dioxide (silica, colloidal anhydrous).

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

Monogramming: black iron oxide, shellac, n-butyl alcohol, isopropyl alcohol, propylene glycol, ammonium hydroxide.

- MAL number:

50mg: MAL24016002ARZ

75mg: MAL24016001ARZ

Manufacturer

Novartis Pharmaceutical Manufacturing LLC
Verovškova ulica 57
1000 Ljubljana
Slovenia

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.
Level 18, Imazium,

No. 8, Jalan SS21/37, Damansara Uptown,
47400 Petaling Jaya, Selangor

PI Version

3 Sep 2025

Date of revision

6 Oct 2025

Serial Number

NPRA (R1) 23/011

NPRA (R1/AI2)19032025/008