

RAHIKA[®] FILM-COATED TABLET

Capmatinib dihydrochloride monohydrate (150mg, 200mg)

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What Rahika is used for

Rahika is a prescription medicine used to treat adults with a kind of lung cancer called non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic), and
- whose tumors have an abnormal mesenchymal epithelial transition (MET) gene

Your doctor will perform a test to make sure that Rahika is right for you.

How Rahika works

Rahika helps to slow down or stop the growth and spread of your lung cancer if it is caused by a change (mutation) in a gene that makes an enzyme called MET.

Before you use Rahika

-When you must not use it

Do not take Rahika if you are allergic to Capmatinib or any of the ingredients in Rahika.

- Before you start to use it

Before you take Rahika, tell your doctor about all of your medical conditions, including if you:

- have or have had lung or breathing problems other than your lung cancer
- have or have had liver problems
- have or have had pancreatic problem
- are pregnant or plan to become pregnant. Rahika can harm your unborn baby.

- are breastfeeding or plan to breastfeed.

- Taking other medicines

Tell your doctor about all the medicines you take or start taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Females who are able to become pregnant

- Your doctor should do a pregnancy test before you start your treatment with Rahika.
- You should use effective birth control during treatment and for 1 week after your last dose of Rahika. Talk to your doctor about birth control choices that might be right for you during this time.
- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with Rahika.

- Breast-feeding

- It is not known if Rahika passes into your breast milk. Do not breastfeed during treatment and for 1 week after the last dose of Rahika.

For males who have female partners who can become pregnant:

- You should use effective birth control during treatment and for 1 week after the last dose of Rahika.

- Children and adolescents

It is not known if Rahika is safe and effective in children.

How to use Rahika

Take Rahika exactly as your doctor tells you to take it.

- How much to use

- Take Rahika exactly as your doctor tells you to take it.

- When to use it

- Take Rahika 2 times a day with or without food.

- How long to use it

- Do not change your dose or stop taking Rahika unless your doctor tells you to.

- If you forget to use it

If you miss or vomit a dose of Rahika, do not make up the dose. Take your next dose at your regular scheduled time.

- If you use too much (overdose)

If you take too much Rahika, contact your doctor or hospital for advice immediately.

While you are using it

- Things you must do

Swallow Rahika tablets whole.

- Things you must not do

Do not break, chew, or crush Rahika tablets.

Medicines are sometimes prescribed for purposes other than those listed in a RiMUP. Do not use Rahika for a condition for which it was not prescribed. Do not give Rahika to other people, even if they have the same symptoms you have. It may harm them.

- Things to be careful of

Your skin may be sensitive to the sun (photosensitivity) during treatment with Rahika. Use sunscreen or wear clothes that cover your skin during your treatment with Rahika to limit direct sunlight exposure.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Rahika may cause serious side effects, including:

- **Lung or breathing problems.** Rahika may cause inflammation of the lungs that can cause death. Tell your doctor right away if you develop any new or worsening symptoms, including:
 - cough
 - fever
 - trouble breathing or shortness of breath
- **Liver problems.** Rahika may cause abnormal liver blood test results. Your doctor should do blood tests to check your liver function before you start treatment and during treatment with Rahika.
- Tell your doctor right away if you develop any signs and symptoms of liver problems, including:
 - Your skin or the white part of your eyes turns yellow (jaundice)
 - dark or 'tea-colored' urine
 - light-coloured stools (bowel movements)
 - confusion
 - tiredness
 - loss of appetite for several days or longer
 - pain, aching, or tenderness on the right side of your stomach-area (abdomen)
 - weakness
 - swelling in your stomach-area
- **Pancreas problems.** Rahika may cause increases in your blood amylase and/or lipase levels that may indicate a problem with your pancreas. Your doctor will do blood tests to check your pancreatic function before you start treatment and during treatment with Rahika.
- Tell your doctor right away if you develop any signs and symptoms of pancreas problems, including:
 - upper stomach (abdominal) pain that may spread to your back and get worse with eating
 - weight loss
 - nausea
 - vomiting

- **Allergic reactions.** Rahika can cause an allergic reaction. Stop taking Rahika and tell your doctor right away if you get any signs and symptoms of an allergic reaction, including:
 - fever
 - chills
 - itching
 - rash
 - dizziness or feeling faint
 - nausea
 - vomiting

- **Risk of sensitivity to sunlight (photosensitivity).** See 'Thing to be careful of'

The most common side effects of Rahika include:

- swelling of your hands or feet
- nausea
- muscle and bone pain
- tiredness and weakness
- vomiting
- trouble breathing
- cough
- loss of appetite
- changes in certain blood tests

Your doctor may change your dose, temporarily stop or permanently stop treatment with Rahika if you develop certain side effects.

These are not all the possible side effects of Rahika. Call your doctor for medical advice about side effects.

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 Rahika

- Storage

- Keep Rahika and all medicines out of the reach of children.
- Do not store above 30°C.
- Protect from moisture
- Do not keep medicine that is out of date or that you no longer need.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

150 mg tablets: Pale orange brown, ovaloid, curved film-coated tablet with beveled edges, unscored, debossed with 'DU' on one side and 'NVR' on the other side.

200 mg tablets: Yellow, ovaloid, curved film-coated tablet with beveled edges, unscored, debossed with 'LO' on one side and 'NVR' on the other side.

- Ingredients

- Active ingredients
 - The active substance of Rahika is Capmatinib.
- Inactive ingredients
 - Tablet Core: colloidal silicon dioxide; crospovidone; magnesium stearate; mannitol; microcrystalline cellulose; povidone; and sodium lauryl sulfate.
 - Coating: ferric oxide, red (150mg); ferric oxide, yellow (150mg & 200mg); ferrousferic oxide (150mg); hypromellose; polyethylene glycol (PEG) 4000; talc; and titanium dioxide.

- MAL Number

Rahika 150mg tablet:
MAL22046004ARZ
Rahika 200mg tablet:
MAL22046005ARZ

Manufacturer

Novartis Pharma Produktions GmbH
Oeflinger Str. 44
79664 Wehr, Germany

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.
Level 18, Imazium,
No. 8, Jalan SS21/37,

Damansara Uptown,
47400 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.

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