

PROTOTYPE 4
RHEUTOPIA® (ROO-TOH-PEE-AH)
(arixalate)

Read this information that comes with RHEUTOPIA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment with RHEUTOPIA.

What is the most important information I should know about RHEUTOPIA?

Serious infections can happen in people who receive RHEUTOPIA. These infections include TB (tuberculosis), and infections caused by viruses, fungi or bacteria. Some people have died from these infections. RHEUTOPIA is a medicine that affects your immune system. RHEUTOPIA can lower the ability of your immune system to fight infections. RHEUTOPIA can make you more likely to get infections or make worse any infection that you have.

Before starting RHEUTOPIA, tell your doctor if you:

- think you have an infection
- are being treated for an infection
- have signs of an infection, such as a fever, cough, or flu-like symptoms
- have any open cuts or sores on your body
- have warm, red, or painful skin
- get a lot of infections or have infections that keep coming back
- have TB, or have been in close contact with someone who has TB.
- have lived in an area where TB is common. If you do not know if you have lived in an area where TB is common, ask your doctor.
- were born in, lived in, or traveled to countries where there is a higher risk for getting TB. Ask your doctor if you are not sure.
- take the medicine Kineret (anakinra) or other medicines that suppress the immune system. You may have a higher chance for serious infections and a low white blood cell count when taking RHEUTOPIA with Kineret or other medicines that can suppress your immune system

Your doctor will examine you for TB and perform a test to see if you have TB before starting RHEUTOPIA. If your doctor feels that you are at risk for TB, you may be treated with a medicine for TB before you begin treatment with RHEUTOPIA and during treatment with RHEUTOPIA. If your doctor prescribes any medicine for the treatment of TB, you should start taking it before starting RHEUTOPIA. Take the full course of TB medicine prescribed. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you take RHEUTOPIA. People who have a negative TB test before receiving RHEUTOPIA can develop active TB.

Call your doctor right away if you get an infection or any of the following symptoms:

- a fever
- feel very tired
- weight loss
- a cough that does not go away
- flu-like symptoms
- have any open cuts or sores on your body
- warm, red, or painful skin

What is RHEUTOPIA?

RHEUTOPIA is a medicine called a Tumor Necrosis Factor (TNF) blocker. RHEUTOPIA is used to treat:

- **moderate to severe rheumatoid arthritis (RA)** in adults. RHEUTOPIA can be used alone or with methotrexate or with certain other medicines.
- **Moderate to severe polyarticular juvenile rheumatoid arthritis (JRA)** in children who have not responded well to other treatments.

- **ankylosing spondylitis (AS)**
- **moderate to severe chronic (lasting a long time) plaque psoriasis (Ps)** in adults who have the condition in many areas of their body and who may benefit from taking injections or pills (systemic therapy) or treatment using ultraviolet light or sunlight and medicine to make your skin sensitive to light (phototherapy).

RHEUTOPIA has not been studied in children younger than 4 years old.

What should I tell my doctor before taking RHEUTOPIA?

Before you take RHEUTOPIA tell your doctor if you:

- have an infection. See “What is the most important information I should know about RHEUTOPIA?”
- have heart failure or other heart conditions. If you have heart failure, it may get worse while you take RHEUTOPIA.
- have any numbness or tingling or have a disease that affects your nervous system such as multiple sclerosis or Guillain-Barre syndrome.
- have recently received or are scheduled for any vaccines. Patients who take RHEUTOPIA should not receive live vaccines.
- are taking Kineret (anakinra). Patients taking Kineret with RHEUTOPIA have a higher chance for serious infections and a low white blood cell count.
- have any other medical condition.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements, especially if you take other medicines that suppress your immune system. See “What is the most important information I should know about RHEUTOPIA?”

Know the medicines you take. Keep a list of your medicines to show your doctor and pharmacist each time you get a new medicine.

Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. RHEUTOPIA should only be used during a pregnancy if needed. Women who are breastfeeding should talk to their doctor about whether or not to use RHEUTOPIA.

Pregnancy Registry: The manufacturer of RHEUTOPIA has a registry for pregnant women who take RHEUTOPIA. The purpose of this registry is to check the health of the pregnant mother and her child. Talk to your doctor if you are pregnant and contact the registry at 1-800-555-5555.

How should I take RHEUTOPIA?

See the section, “**How do I prepare and give an injection of RHEUTOPIA?**” for complete instructions for use.

- RHEUTOPIA is given by an injection under the skin, one or two times every week. Your doctor will tell you how often to take an injection of RHEUTOPIA.
- Make sure you have been shown how to inject RHEUTOPIA before you do it yourself. You can call your doctor or 1-800-RHEUTOPIA if you have any questions about giving yourself an injection. Someone you know can also help you with your injection.
- **Do not inject more RHEUTOPIA or more often than your doctor prescribed.** If you take more RHEUTOPIA than you were told to take, call your doctor.

- Do not miss any doses of RHEUTOPIA. If you forget to take RHEUTOPIA, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. This will put you back on schedule.

What are the possible side effects of RHEUTOPIA?

Serious side effects can happen in people who take RHEUTOPIA, including:

See “**What is the most important information I should know about RHEUTOPIA?**”

- **Lymph node cancer.**
 - People who take RHEUTOPIA can get lymph node and other kinds of cancer.
 - People with more serious RA that have the disease for a long time may have a higher chance for getting lymph node cancer (called lymphoma).
- **Nervous system problems.** Signs and symptoms of a nervous system problem include: numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- **Blood problems.** Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **New heart failure or worsening of heart failure you already have.** Symptoms include shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- **Immune reactions including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on your cheeks or arms that gets worse in the sun. Symptoms may go away when you stop RHEUTOPIA.

Call your doctor or get medical care right away if you develop any of the above symptoms.

Common side effects with RHEUTOPIA include:

- **Injection site reactions** such as redness, rash, swelling, itching, or bruising. If you have pain, redness or swelling around the injection site that does not go away within a few days or gets worse, call your doctor right away.
- **Infections (upper respiratory infections)**
- **Headaches**
- **Runny nose**

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects with RHEUTOPIA. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store RHEUTOPIA?

- Store RHEUTOPIA in a refrigerator between 36°F to 46°F (2°C to 8°C) in the original container until it is used.
- Protect from light.
- **Do not freeze RHEUTOPIA.** If your RHEUTOPIA has been frozen, do not use it, even after it has thawed.
- Refrigerated RHEUTOPIA in the single-use prefilled syringe can be used until the expiration date printed on the prefilled syringe.
- RHEUTOPIA in the multiple-use vial must be thrown away 14 days after being mixed.
- Do not shake RHEUTOPIA.

Keep RHEUTOPIA, injection supplies, and all other medicines out of the reach of children.

General information about RHEUTOPIA

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

This information summarizes the most important information about RHEUTOPIA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about RHEUTOPIA that was written for healthcare professionals.

For more information or to enroll in a patient support program, call (manufacturer) at 1-800-123-4567 or visit www.RHEUTOPIA.com.

What are the ingredients in RHEUTOPIA?

Active ingredient: arixalate

Inactive ingredients:

- **Single-use prefilled syringe:** sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous.
- **Multiple-use vial:** mannitol, sucrose, tromethamine

This information has been approved by the U.S. Food and Drug Administration.

Name and place of business of the manufacturer

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