

Rheutopia [Roo-TOH-pee-ah] (also known as arixalate)

Uses

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

- Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection.
- People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Tell your doctor before using Rheutopia if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB. You may be tested and treated for TB.
- have any nervous system or heart problems.
- have lived in or traveled to other countries. There is more risk for getting TB or other infections in certain countries.
- have been recently been vaccinated or are scheduled to receive a vaccination (including a flu shot). You should not get a vaccination while taking Rheutopia.
- are taking the medicine Kineret (anakinra). The risk of serious infections increased when used with Rheutopia.

Stop using Rheutopia and call your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection.
- Numbness, tingling, weakness, vision problems, or dizziness. Symptoms of nervous system diseases, like multiple sclerosis, may develop or get worse.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss. You may have a higher chance of getting lymph node cancer.
- Bruising, bleeding, and pale skin. Your body may not make enough blood cells to fight infection or to help stop bleeding.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain. These are symptoms of heart failure that may develop or get worse.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be symptoms of an immune reaction with lupus-like syndrome.

Common side effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for use

- Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Rheutopia [Roo-TOH-pee-ah] (also known as arixalate)

Uses

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

- Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection.
- People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Tell your doctor before using Rheutopia if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB. You may be tested and treated for TB.
- have any nervous system or heart problems.
- have lived in or traveled to other countries. There is more risk for getting TB or other infections in certain countries.
- have been recently been vaccinated or are scheduled to receive a vaccination (including a flu shot). You should not get a vaccination while taking Rheutopia.
- are taking the medicine Kineret (anakinra). The risk of serious infections increased when used with Rheutopia.

Stop using Rheutopia and call your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection.
- Numbness, tingling, weakness, vision problems, or dizziness. Symptoms of nervous system diseases, like multiple sclerosis, may develop or get worse.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss. You may have a higher chance of getting lymph node cancer.
- Bruising, bleeding, and pale skin. Your body may not make enough blood cells to fight infection or to help stop bleeding.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain. These are symptoms of heart failure that may develop or get worse.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be symptoms of an immune reaction with lupus-like syndrome.

Common side effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for use

- Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.