

RIDAURA®

3 mg Film-coated tablets

Auranofin

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Ridaura.

This leaflet answers some of the common questions about Ridaura. It does not contain all the available information.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ridaura against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Ridaura is used for

Ridaura contains auranofin, a synthetic gold compound. It is used together with other treatments, such as non-steroidal anti-inflammatory drugs (NSAIDs), for active rheumatoid arthritis.

It is thought to modify the progress of active rheumatoid arthritis.

Ridaura may prevent or reduce further damage to the joints.

Ridaura can also reduce the inflammation in the joints.

Rheumatoid arthritis can affect most joints, but the small joints of the hands and feet are frequently

affected. The joints become swollen, warm and tender. This leads to pain and loss of joint movement. Deformity occurs with time. Morning stiffness in affected joints is a common symptom of rheumatoid arthritis.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have questions about why it has been prescribed for you.

Ridaura is only available with a doctor's prescription.

There is no evidence that Ridaura is addictive.

Before you take Ridaura

When you must not take it

Do not take Ridaura if:

- you have previously had a severe reaction to Ridaura, or to other products containing gold (e.g. Myocrisin, Gold-50) or other heavy metals, or you have had lung or gut problems caused by gold
- you have or have had any of the following medical conditions:
 - severe liver problems
 - progressive kidney disease
 - severe blood disorder
 - bone marrow disorder, e.g. due to disease or other medicine, chemical or radiation
 - confirmed or suspected systemic lupus erythematosus (SLE)
 - severe chronic skin disease

such as severe eczema, hives or dermatitis.

Do not take Ridaura if you are allergic to:

- auranofin or any of the ingredients listed at the end of this leaflet
- gold or any other heavy metal.

Do not take Ridaura if you are already taking:

- any medicine that affects the bone marrow, including some medicines used to treat cancer
- clozapine, used to treat schizophrenia
- penicillamine, used to treat rheumatoid arthritis
- leflunomide, high dose corticosteroids and other immunosuppressants (medicines which reduce the activity of your immune system)
- medicines used to prevent or treat malaria, e.g. chloroquine, hydroxychloroquine, atovaquone, proguanil, mefloquine or quinine

Do not take it after the expiry date ('Exp.') printed on the pack.

If the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

- you have or have had allergies to any other medicines, foods, preservatives or dyes

- **you are prone to allergies in general, including allergic skin reactions, hay fever or asthma**
- **you have or have had:**
 - any liver problems
 - any kidney problems
 - inflammatory bowel disease
 - Sjogren's syndrome, an autoimmune disease
 - diabetes mellitus
 - heart failure or high blood pressure
 - systemic sclerosis
 - skin rashes
 - porphyria, a rare blood pigment disorder
 - inherited intolerance to sugar, including galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption
 - recent or current treatment with radiotherapy.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Ridaura should not be used during pregnancy.

Tell your doctor if you are breast-feeding, or planning to breast-feed.

Ridaura passes into breast milk and may affect your baby.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Ridaura.

Do not give Ridaura to a child or adolescent.

There is no experience with its use in children or adolescents under 16 years old.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell any health professional who is prescribing a new medicine for you that you are taking Ridaura.

Some medicines and Ridaura may interfere with each other. These include:

- medicines listed above under "When you must not take it"
- clonidine, a medicine used to treat high blood pressure
- corticosteroids, used in the treatment of many diseases including rheumatoid arthritis
- medicines used to control pain, such as dextropropoxyphene
- aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) including phenylbutazone and oxyphenbutazone
- medicines known as ACE inhibitors, used to treat high blood pressure and heart failure
- chelating agents, used to remove metals like copper, gold and mercury from the body
- some antibiotics, including aminoglycosides, amphotericin B, penicillins and sulphonamides
- aciclovir, used to treat viral infections
- phenytoin, used to treat epilepsy
- any medicine that affects gut motility including laxatives, e.g. senna, and treatments for diarrhoea, e.g. loperamide
- theophylline, used to treat asthma
- warfarin, used to prevent blood clots
- levamisole, a treatment for worm infections
- quinidine.

The above medicines may be affected by Ridaura, or may affect how well it works. You may need to use different amounts of Ridaura, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking this medicine.

How to take Ridaura

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The usual dose of Ridaura for rheumatoid arthritis is two 3 mg tablets per day.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Ridaura may not work as well and your problem may not improve.

Take Ridaura with a full glass of water.

When to take it

Ridaura may be taken as either a single daily dose (2 tablets once a day) or twice daily (one tablet twice a day).

Take Ridaura during or immediately after a meal, at about the same time(s) each day.

How long to take it

Continue taking the medicine for as long as your doctor tells you to.

It may take 3 to 4 months (or more) before Ridaura has any effect. Your doctor may decide that you should continue to use Ridaura for some time, even when your symptoms subside.

Do not stop taking Ridaura even if you begin to feel better.

For best effect Ridaura must be taken regularly.

If you are unsure whether you should stop taking Ridaura, talk to your doctor or pharmacist.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Ridaura.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include dizziness, headache, flushing, fast or irregular heart beat or any of the side effects mentioned below.

While you are taking it

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Ridaura. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Treatment with Ridaura requires careful monitoring. You will have regular blood, liver and urine tests and eye examinations.

Tell your doctor promptly if you start having any unusual symptoms such as:

- itching, rash
- metallic taste
- mouth ulcer, sore throat or tongue
- easy bruising, red-purple spots on the skin
- nose bleed or bleeding gums
- diarrhoea
- abnormally heavy periods in women

These are some of the possible symptoms of gold toxicity. You may need immediate medical attention.

If you are a woman, you must take measures to avoid pregnancy during treatment and for at least 6 months after stopping treatment with Ridaura.

Ridaura should not be used in pregnant women because of the possible risk of birth defects.

Pregnancy must be avoided after stopping treatment because it takes some time for gold to be removed from the body.

Tell your doctor immediately if you become pregnant during treatment or within 6 months of stopping treatment.

Your doctor will discuss with you the risks and options if this occurs.

Things you must not do

Do not take Ridaura to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking Ridaura or lower the dosage without checking with your doctor.

For best effect Ridaura must be taken regularly.

Things to be careful of

Protect your skin when you are in the sun, especially between 10am and 3pm. If you are outdoors, wear protective clothing and use a 30+ sunscreen.

Ridaura may cause your skin to be much more sensitive to sunlight than it is normally. This could cause a skin rash, itching, redness or severe sunburn.

Talk to your doctor or pharmacist and follow their advice about drinking alcohol while being treated with Ridaura

Depending on your particular medical condition and other treatments, your doctor or pharmacist may recommend you limit or stop drinking alcohol while taking Ridaura.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ridaura.

Like all medicines, Ridaura may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- mild stomach pains or cramps
- gas from the stomach or bowel
- nausea or vomiting
- indigestion
- constipation
- loss of appetite

- increased sensitivity to sunlight
- hair loss
- diarrhoea.

The above list includes the more common side effects of your medicine. These side effects are usually mild.

Diarrhoea is a common side effect with Ridaura. The severity of the diarrhoea can be affected by the amount of Ridaura you take. It may be necessary for your doctor to change how much or how often you take Ridaura.

Tell your doctor immediately if you notice any of the following:

- metallic taste
- sore throat, tongue or mouth, or mouth ulcers
- itching, rash, redness or peeling of the skin
- easy bruising or bleeding, red-purple spots on the skin
- abnormally heavy periods in women
- sore eyes or eye changes
- blood in the urine
- yellowing of the skin or eyes (jaundice)
- blood in vomit or stools, or black, tarry stools
- stomach pains or cramps that are severe, persist or recur
- unintended weight loss
- shortness of breath or coughing, particularly if accompanied by fever, fatigue or loss of appetite.

These may be serious side effects. You may need urgent medical attention.

Stop taking Ridaura and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing).

This is a very serious side effect. You may need urgent medical attention or hospitalisation.

Some side effects may only be found when your doctor does laboratory tests to check your progress, e.g. low blood cell counts, changes in the urine, some effects on liver and kidney function.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in the original pack until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep the medicine in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Return any unused medicine, and any medicine past its expiry date (as shown on the dispensing label or on the packaging) to your pharmacist.

Product description

What it looks like

Ridaura is available in bottles of 60 tablets. The tablets are square, bevel-edged, and pale yellow.

Ingredients

Active ingredient:

- 3mg auranofin per tablet

Inactive ingredients:

- **lactose monohydrate**
- maize starch
- microcrystalline cellulose
- sodium starch glycollate
- magnesium stearate
- hypromellose
- propylene glycol
- titanium dioxide
- iron oxide yellow (CI77492).

Ridaura tablets contain lactose monohydrate. They do not contain sucrose, tartrazine or any other azo dyes.

Sponsor details

Amdipharm Mercury (Australia) Pty Ltd
Level 9, 76 Berry Street
North Sydney NSW 2060
AUST R 13000

Date of preparation

This leaflet was revised on 1 May 2020.

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