What is 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 heavy metals
- you have any of the following medical conditions:
  - liver problems
  - kidney problems
  - severe blood or bone marrow disorders
  - severe chronic skin disease such as eczema, hives or dermatitis.
Do not take Ridaura if you are allergic to any medicine containing auranofin or any of the ingredients listed at the end of this leaflet.

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 allergies to any other medicines, foods, preservatives or dyes**
- **you are pregnant or intend to become pregnant.** Like most medicines of this kind, Ridaura should not be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.
- **you are breast-feeding, or planning to breast-feed.** Ridaura passes into breast milk and may affect your baby.
- **you have, or have had, the following medical conditions:**
  - liver problems
  - kidney problems
  - severe blood or bone marrow disorders
  - severe, chronic skin disease such as eczema, hives or dermatitis
  - a history of allergies
  - inflammatory bowel disease
  - systemic lupus erythematosus (SLE)
  - Sjogren’s syndrome, an autoimmune disease
  - diabetes
  - heart failure or high blood pressure
  - systemic sclerosis.

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:

- penicillamine, used to treat rheumatoid arthritis
- high dose corticosteroids and other immunosuppressants (medicines which reduce the activity of your immune system)
- medicines used to prevent or treat malaria, for example chloroquine and hydroxychloroquine
- medicines used to treat cancer
- clonidine, a medicine used to treat high blood pressure
- medicines used to control pain, such as dextropropoxyphene, phenylbutazone
- warfarin, a medicine used to prevent blood clots
- levamisole, a treatment for worm infections.
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 3mg 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 our 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.

**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.

**Things you must not do**

Do not give your medicine to anyone else, even if they have the same condition as you. This medicine is only intended for the use of the patient it has been prescribed for.

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

**In case of overdose**

**If you take too much**

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.

**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.

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:
- stomach pains or cramps
- gas from the stomach or bowel
- nausea or vomiting
- constipation
- heartburn
- loss of appetite
- hair loss
- diarrhoea.

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 tongue or mouth, or mouth ulcers
- itching
- rash
- easy bruising or bleeding
- sore eyes or eye changes
- blood in the urine
- jaundice or liver problems
- kidney problems
- low blood cell counts
- gastrointestinal bleeding, peptic ulcer
- lung inflammation.

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.

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

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

**Sponsor details**

Amdipharm Mercury (Australia) Pty Ltd
Level 1, 134 Willoughby Road
Crows Nest NSW 2065

AUST R 13000
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This leaflet was prepared on 09 February 2016.

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