

RIDAURA™

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about RIDAURA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read this leaflet before you start taking RIDAURA. If you are helping someone else take RIDAURA, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor has weighed the possible risks of taking RIDAURA against the expected benefits.

Keep this leaflet with the medication. You may want to read it again.

WHAT RIDAURA IS USED FOR

The name of your medicine is RIDAURA also known as auranofin.

RIDAURA is a synthetic gold compound. 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.

RIDAURA is used together with other treatments, such as nonsteroidal anti-inflammatory drugs (NSAIDs), for active rheumatoid arthritis

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. Your doctor may have prescribed RIDAURA for another use. Ask your doctor if you have questions about why RIDAURA has been prescribed for you.

There is no evidence that RIDAURA is addictive.

BEFORE TAKING RIDAURA

DO NOT TAKE RIDAURA IF:

- you have had an allergic reaction to RIDAURA or to any of the ingredients listed in the **Product Description** section of this leaflet. Signs of allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- you have taken RIDAURA before and became unwell, tell your doctor or pharmacist before taking the first dose.
- you have had a severe reaction to RIDAURA or to other products containing gold (eg. Myocrisin, Gold-50) or heavy metals.
- you have any of these medical conditions:
 - liver problems
 - kidney problems
 - severe blood or bone marrow disorders
 - severe, chronic skin disease such as eczema, hives or dermatitis
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

There is no specific information available to recommend the use of RIDAURA in children.

Do not give this medicine to anyone else. Your doctor has prescribed it specifically for you and your condition.

BEFORE YOU START TAKING RIDAURA TELL YOUR DOCTOR IF:

- you have had an allergic reaction to any medicine which you have taken previously to treat your current condition.
- you are pregnant or intend to become pregnant. *Your doctor will discuss with you the possible risks and benefits of using RIDAURA during pregnancy.*
- you are breastfeeding, or wish to breastfeed. *Your doctor will discuss with you the possible risks and benefits of using RIDAURA during breastfeeding.*
- you have any of these medical conditions:
 - liver problems
 - kidney problems
 - severe blood or bone marrow disorders
 - severe, chronic skin disease such as eczema, hives or dermatitis
 - inflammatory bowel disease
 - thickening of the lungs
 - systemic lupus erythematosus (SLE)
 - Sjogren's syndrome
 - diabetes, heart failure or high blood pressure

TAKING OTHER MEDICINES WITH RIDAURA

Tell your doctor if you are taking any other medicines or have used other medicines until recently. This includes those that you buy without a prescription. In particular tell your doctor if you are taking any of the following medicines which:

- treat rheumatoid arthritis (D-penamine, Plaquenil, Imuran, Cycloblastin, Butazolidin, high dose corticosteroids).
- lower blood pressure or treat migraine (Catapres)
- control pain, such as propoxyphene (Di-Gesic, Doloxene, Capadex, Paradex)
- thin blood (anti-coagulants), such as warfarin (Coumadin, Marevan)

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you which medicines are safe to take with RIDAURA.

HOW TO TAKE RIDAURA

Follow your doctor's instructions about how and when to take RIDAURA.

Read the direction label carefully. If you have any concerns about how to take RIDAURA, talk to your doctor or pharmacist.

HOW MUCH TO TAKE

The usual dose of RIDAURA for rheumatoid arthritis is two 3mg tablets per day. RIDAURA may be taken as either a single daily dose or twice daily.

HOW AND WHEN TO TAKE IT

Take RIDAURA with a full glass of water or another liquid. RIDAURA should be taken with food.

HOW LONG TO TAKE IT

Keep taking your RIDAURA for as long as your doctor tells you to. Remember it may take a number of months for RIDAURA to work.

Do not stop taking RIDAURA even if you begin to feel better. For best effect RIDAURA must be taken regularly.

IF YOU FORGET TO TAKE IT

Do not take an extra dose. Wait until it is time for the next dose and take your normal dose then.

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

OVERDOSE

Immediately telephone your doctor or Poisons Information Centre (13 11 26 in Australia or 0800 764766 in New Zealand) for advice or go to the Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much RIDAURA. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE USING RIDAURA

THINGS YOU MUST DO:

- Check with your doctor, pharmacist or dentist before taking any other medicines. This includes medicines that you buy without a prescription as well as prescribed medicines.
- Treatment with RIDAURA requires careful monitoring by your doctor. Be sure to keep your appointments with your doctor.
- Have regular blood, liver and urine tests and eye examinations.

THINGS TO BE CAREFUL OF:

Avoid direct sunlight. RIDAURA can increase the effects of the sun on the skin. You may develop a rash on sun-exposed areas. Wear a hat and cover up as much as possible when in direct sunlight. Use SPF-15 sunblock on uncovered skin.

SIDE EFFECTS

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

Like other medicines, RIDAURA can cause some side effects. If they occur they may be mild, and may become less after a few days. However, some may be serious and need medical attention.

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.

MILD EFFECTS:

Tell your doctor if you notice any of the following that are troublesome or ongoing:

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

MORE SERIOUS EFFECTS

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

- metallic taste
- itching

- sore tongue or mouth or mouth ulcers
- rash
- easy bruising or bleeding
- sore eyes
- blood in the urine

Stop taking RIDAURA and contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:

- allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing.

OTHER RARE EVENTS THAT HAVE BEEN REPORTED WITH RIDAURA INCLUDE

- jaundice or liver problems
- low blood cell counts
- gastrointestinal bleeding, peptic ulcer
- lung inflammation
- kidney disease
- eye changes

This is not a complete list of all possible events reported. Other events may occur in some people and there may be some unwanted effects not yet known. Remember to tell your doctor as soon as possible if you do not feel well when you are taking or soon after you have stopped taking RIDAURA.

STORAGE

Keep your tablets in the original pack until it is time to take them. Keep the pack in a cool dry place. Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Store all medicines out of the reach of children such as in a locked cupboard.

If your doctor tells you to stop taking RIDAURA, ask your pharmacist what to do with any tablets that are left over.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

RIDAURA comes as a square, bevel-edged, pale yellow tablet, containing 3mg of auranofin.

OTHER INGREDIENTS

RIDAURA tablets contain lactose, maize starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, hydroxypropylmethyl cellulose, propylene glycol, titanium dioxide (C177891) and iron oxide yellow (C177492).

RIDAURA tablets do not contain sucrose, tartrazine or any other azo dyes.

FURTHER INFORMATION

RIDAURA tablets are only available if prescribed by a doctor.

RIDAURA comes in packs of 60 tablets (AUST R 13000).

SPONSOR

Goldshield Healthcare (Australia) Pty. Ltd.
Level 1, 118-124 Willoughby Road
CROWS NEST, NSW 2065
Australia

Boucher & Muir (NZ) Ltd t/a Goldshield Healthcare (NZ)
39 Anzac Road,
Browns Bay,
Auckland 0753,
New Zealand

Date of leaflet preparation: 15 November 2001

Last amended: 25 January 2010