

# Myocrisin<sup>®</sup>

Sodium aurothiomalate

## Consumer Medicine Information (CMI)

### What is in this leaflet

This leaflet answers some common questions about Myocrisin.

It does not contain all the available information. It 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 being given this medicine against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Myocrisin is used for

Myocrisin is a type of medicine used to help treat rheumatoid arthritis and Still's disease (a form of arthritis in children).

Myocrisin helps to reduce the inflammation which can occur with arthritis.

Your doctor, however, may prescribe Myocrisin for another purpose.

**Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.**

This medicine is only available with a doctor's prescription.

### Before you are given it

#### *When you must not be given it*

**Do not receive Myocrisin if you have:**

- liver disease
- kidney disease
- diabetes
- blood disorders or a history of blood disorders
- any serious skin disorders
- are pregnant or plan to become pregnant
- history of systemic lupus erythematosus, a disease affecting the skin, joints and kidneys

**Do not receive Myocrisin if you are allergic to it or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

**Do not use Myocrisin if the solution has darkened in colour.**

Any solution darker than a pale yellow should not be used.

**Do not receive it if you are pregnant or intend to become pregnant.**

It may affect your developing baby if you are given it during pregnancy.

**Do not receive it if you are breastfeeding or planning to breastfeed.**

Myocrisin passes into breast milk and there is a possibility your baby may be affected.

**Do not receive it after the expiry date (EXP) printed on the pack.**

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

**Do not receive it if the packaging is damaged or shows signs of tampering.**

#### *Before you are given it*

**Tell your doctor if you have allergies to:**

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

Like most medicines of this kind, Myocrisin is not recommended to be used during pregnancy.

**Tell your doctor if you are breastfeeding or planning to breastfeed.**

Myocrisin passes into breast milk and there is a possibility your baby may be affected.

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- liver disease
- kidney disease
- diabetes
- blood disorders

- heart or brain disorders
- high blood pressure
- any serious skin disorders
- urticaria or eczema
- inflammation of the bowel causing severe diarrhoea
- scarring and thickening in the lungs with shortness of breath

Before you start receiving Myocrisin, and before each treatment you doctor may conduct laboratory tests and examine your skin.

**Tell your doctor if you plan to have surgery.**

**If you have not told your doctor or about any of the above, tell them before you are given Myocrisin.**

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.**

Some medicines may interfere with Myocrisin. These include:

- penicillamine, a medicine for treating rheumatoid conditions and for treating heavy metal poisoning
- phenylbutazone or oxyphenbutazone, medicine for treating inflammation and fever
- aspirin
- angiotensin-converting enzyme inhibitors, a type of medicine for treating heart problems.

These medicines may be affected by Myocrisin, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given Myocrisin.

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## **How it is given**

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### ***How much to be given***

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

### ***How it is given***

This medicine is given as an injection into the muscle by a doctor or trained nurse. It is likely that you will remain under supervision of your doctor for 30 minutes after you have received it.

### ***How long it will be given***

**Continue receiving your medicine for as long as your doctor tells you.**

The medicine helps control your condition, but it does not cure it.

### ***If you receive too much (overdose)***

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

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## **While you are being given it**

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### ***Things you must do***

**Tell all the doctors, dentists and pharmacists who are treating you that you are being given Myocrisin.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being given Myocrisin.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.**

**If you become pregnant while you are being given this medicine, stop using it and tell your doctor or pharmacist immediately.**

**Be careful driving or operating machinery until you know how Myocrisin affects you.**

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## **Side effects**

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All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

You may not experience any of them.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Myocrisin.**

It helps most people with arthritis, but it may have unwanted side effects in a few people.

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

**Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- a skin rash or skin problems
- eye problems or blurred vision
- metallic taste in the mouth
- yellowing of the skin and/or eyes
- mouth ulcers and/or inflammation of the tongue
- your skin becomes pale, you start to feel tired, you become prone to infections or bruising
- diarrhoea, abdominal pain and/or nausea and vomiting
- dizziness or feeling faint
- temporary inflammation of the nerves, causing pain, weakness, and paralysis in the extremities and often progressing to the chest and face

These may be serious side effects of Myocrisin. You may need urgent

medical attention. Serious side effects are uncommon.

**If any of the following happen, stop receiving this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- **swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing**
- **hives**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Myocrisin. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

Other side effects not listed above may occur in some consumers.

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

You may not experience any of them.

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

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## After being given it

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**If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.**

### **Storage**

**Myocrisin should be stored in the pharmacy or in the ward. Keep the medicine in a cool, dry place, protected from light where the temperature stays below 25°C.**

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## Product description

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### **What it looks like**

Myocrisin is a clear solution contained within 1 mL ampoules for injection.

Myocrisin is available in boxes of 10 ampoules

### **Ingredients**

Active Ingredient:

Myocrisin 10mg (2%) - 10mg sodium aurothiomalate per 0.5mL

Myocrisin 20mg (4%) - 20mg sodium aurothiomalate per 0.5mL

Myocrisin 50mg (10%) - 50mg sodium aurothiomalate per 0.5mL

Inactive Ingredients:

- phenylmercuric nitrate
- water for injection

Myocrisin does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

### **Manufacturer/Sponsor**

Myocrisin is made in Italy.

Myocrisin is supplied in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Myocrisin is supplied in New Zealand by:

sanofi -aventis new zealand limited

Level 8, 56 Cawley Street

Ellerslie

Auckland

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Australian Register Number(s)

10mg Ampoule: AUST R 27518

20mg Ampoule: AUST R 27519

50mg Ampoule: AUST R 27521

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