

Oruvail SR[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Oruvail SR?

Oruvail SR contains the active ingredient ketoprofen. Oruvail SR is used to treat the symptoms of rheumatoid arthritis and osteoarthritis. Oruvail SR belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

For more information, see Section [1. Why am I using Oruvail SR?](#) in the full CMI.

2. What should I know before I use Oruvail SR?

Do not use if you have ever had an allergic reaction to ketoprofen, aspirin or any other anti-inflammatory drugs, or any of the ingredients listed at the end of the CMI.

Do not use if you have a peptic ulcer; problems with your heart; severe kidney or liver problems.

Do not use if you are in your third trimester of pregnancy.

The use of Oruvail SR during the first and second trimester of pregnancy should be avoided, as the safety of Oruvail SR in pregnant women has not been evaluated.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Oruvail SR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Oruvail SR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Oruvail SR?

- The usual dose for this medicine is 200mg taken once a day, with food and plenty of fluids.
- Follow the instructions provided and use Oruvail SR until your doctor tells you to stop.

More instructions can be found in Section [4. How do I use Oruvail SR?](#) in the full CMI.

5. What should I know while using Oruvail SR?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Oruvail SR.• Call your doctor straight away if you become pregnant while you are taking this medicine• Call your doctor straight away if you get an infection while taking Oruvail SR |
| Things you should not do | <ul style="list-style-type: none">• Do not take more than the recommended dose unless your doctor tells you to.• Do not take if you have a history of bleeding or ruptured gut, related to previous NSAIDs therapy. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Oruvail SR affects you. |
| Looking after your medicine | <ul style="list-style-type: none">• Store it in a cool (below 25°C), dry place away from moisture, heat or sunlight. |

For more information, see Section [5. What should I know while using Oruvail SR?](#) in the full CMI.

6. Are there any side effects?

There are a number of serious side effects associated with this medicine. It is important to be aware of them so you can identify any symptoms if they occur.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Oruvail SR[®]

Active ingredient: *Ketoprofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Oruvail SR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Oruvail SR.**

Where to find information in this leaflet:

- [1. Why am I using Oruvail SR?](#)
- [2. What should I know before I use Oruvail SR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Oruvail SR?](#)
- [5. What should I know while using Oruvail SR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Oruvail SR?

Oruvail SR contains the active ingredient ketoprofen.

Oruvail SR belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

Oruvail SR relieves pain and reduces inflammation (swelling, redness and soreness) that may occur in rheumatoid arthritis or osteoarthritis.

Oruvail SR is used to treat the symptoms of rheumatoid arthritis and osteoarthritis. Although Oruvail SR can relieve the symptoms of pain and inflammation, it will not cure your condition.

2. What should I know before I use Oruvail SR?

Warnings

Do not use Oruvail SR if:

- you have a peptic ulcer (e.g., a stomach ulcer), or have had peptic ulcers before
- you have a history of bleeding or ruptured gut, related to previous NSAIDs therapy
- you have problems with your heart
- you have severe kidney or liver disease
- you are in your third trimester of pregnancy
- you are allergic to aspirin or any other anti-inflammatory medicines.
- you are allergic to ketoprofen, or any of the ingredients listed at the end of this leaflet.
- you are in the last 3 months of pregnancy

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.

Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

- **have allergies to:**
 - any of the ingredients listed at the end of this leaflet
- **have any other medical conditions, especially:**
 - heartburn, indigestion, stomach ulcer or other stomach problems
 - bowel or intestinal problems such as ulcerative colitis
 - kidney or liver disease
 - high levels of potassium in your blood
 - eye problems
 - high blood pressure or heart problems
 - swelling of hands, ankles or feet
 - a tendency to bleed or other blood problems
 - asthma or a history of asthma
 - skin problems or a history of skin problems or allergic reaction
- take any medicines for any other condition
- plan to have surgery
- if you are over 65 and unwell or taking other medicines
- currently have an infection.

If you take Oruvail SR while you have an infection, Oruvail SR may hide some of the signs of an infection such as fever and pain. This may make you think, mistakenly, that you are better or that it is not serious.

It is therefore possible that Oruvail SR may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Talk to your doctor or pharmacist before taking Oruvail SR, to discuss if you have ever developed fixed drug eruption (round or oval patches of redness and swelling of the skin that usually recurs at the same site(s), blistering, hives and itching) with this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

- Do not use if you are in your third trimester of pregnancy.
Taking Oruvail around 13 weeks of pregnancy or later may harm your unborn baby. If you need to take Oruvail for more than 2 days when you are between

13 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. **You should not take Oruvail after 6 months of pregnancy.**

- Do not take Oruvail SR if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labor to be later or longer than expected.
- You should not take Oruvail SR during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 13 weeks of pregnancy onward, Oruvail SR can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

It may affect your developing baby if you take it during pregnancy. Like most NSAIDs, Oruvail SR is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

- Do not take it if you are breastfeeding or planning to breastfeed.

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

Use in children

- Do not give Oruvail SR to a child or adolescent.

Oruvail SR is not recommended for use in children as there have been no studies of its effects in children.

3. What if I am taking other medicines?

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

Some medicines may interfere with Oruvail SR and affect how it works.

- aspirin, salicylates or other NSAID eg. Ibuprofen (anti-inflammatory) medicines
- anticoagulants, sometimes called 'blood thinners', such as warfarin, and other medicines used to treat or prevent blood clots
- medicines used to treat some types of depression or epilepsy (eg. lithium)
- certain medicines used to treat cancer and arthritis such as methotrexate
- diuretics, also called fluid or water capsules
- trimethoprim, a medicine used to prevent or treat urinary tract infections

- medicines used to treat high blood pressure or various heart conditions
- probenecid, a medicine used to treat gout
- pentoxifylline (oxpentifylline), a medicine used to improve the circulation of the blood
- medicines used to help prevent organ transplant rejection or certain problems with the immune system (eg. ciclosporin, tacrolimus)
- steroids (eg, corticosteroids such as hydrocortisone)
- some medicines used to treat depression (eg. SSRIs such as fluoxetine)
- some medicines used to treat HIV (eg. tenofovir)
- some contraceptive devices (e.g., intrauterine devices)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Oruvail SR.

4. How do I take Oruvail SR?

How much to take

- The usual dose for this medicine is 200mg taken once a day, with food and plenty of fluids.
- Follow the instructions provided and use Oruvail SR until your doctor tells you to stop.
- The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

When to take Oruvail SR

- Take Oruvail SR at about the same time each day.
- Depending on your condition, you may need Oruvail SR for a few days, a few weeks or for longer periods.

As with other NSAID medicines, if you are using Oruvail SR for arthritis, it will not cure your condition, but it should help to control pain, swelling and stiffness. If you have arthritis, Oruvail SR should be taken every day for as long as your doctor prescribes.

If you forget to take Oruvail SR

Oruvail SR should be taken regularly at the same time each day.

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

If you miss your dose at the usual time, and if there is still a long time until your next dose, take it as soon as you remember. Then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

If you take too much Oruvail SR

If you think that you have used too much Oruvail SR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling Australia 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Oruvail SR?

Things you should do

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking Oruvail SR.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Oruvail SR.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

Call your doctor straight away if you:

- become pregnant while you are taking this medicine.
- get an infection while taking Oruvail SR.
- develop fixed drug eruption. You should stop taking Oruvail SR if this occurs.

Oruvail SR may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling, redness.

Remind any doctor, dentist or pharmacist you visit that you are using Oruvail SR.

Things you should not do

- Do not take more than the recommended dose unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Oruvail SR, or lower the dosage, without checking with your doctor or pharmacist.
- Do not stop taking your capsules because you are feeling better, unless advised by your doctor or pharmacist.

Things that may help your condition

Some self-help measures suggested as follows may help your condition.

Talk to your doctor, physiotherapist or pharmacist about them:

- Weight and diet

Your doctor may suggest losing some weight to reduce the stress on your joints. Eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.

- Exercise

Regular exercise may be recommended by your doctor or physiotherapist to help keep or improve movement and strengthen muscles. Before starting any exercise, ask your

doctor or physiotherapist about the best kind of program for you.

- Rest

Rest is important and is usually balanced with exercise and activity. Rest is needed when joints are hot, swollen or painful.

- Heat

Hot showers or baths may help to ease the pain and relax the muscles that can become tense with arthritis. Your physiotherapist or doctor can prescribe other forms of heat treatment.

- Physical aids

Are available to help with daily household tasks. For example, there are gadgets and aids to help turn on taps, remove screw tops, pick up objects and handles can be fitted in bathrooms. Ask your doctor to give you information.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Oruvail SR affects you.

It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store in a cool (below 25°C), dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>Gastrointestinal-related</p> <ul style="list-style-type: none"> stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps loss of appetite constipation, diarrhoea, pain in the stomach, wind ulcers <p>Nervous system-related</p> <ul style="list-style-type: none"> dizziness drowsiness headache disorientation buzzing or ringing in the ears <p>Skin-related</p> <ul style="list-style-type: none"> dry or itchy skin rash sore or dry mouth or tongue <p>Other</p> <ul style="list-style-type: none"> weight loss | <p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <p>Gastrointestinal-related</p> <ul style="list-style-type: none"> severe pain or tenderness in the stomach vomiting blood or material that looks like coffee grounds bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea <p>Heart and blood-related:</p> <ul style="list-style-type: none"> Worsening of heart failure (symptoms of heart failure include shortness of breath, tiring easily after light exercise and swollen ankles & feet). pain or tightness in the chest fast or irregular heartbeats, also called palpitations signs of anaemia, such as tiredness, being short of breath, and looking pale <p>Kidney and liver-related</p> <ul style="list-style-type: none"> bleeding or bruising more easily than normal, reddish or purplish blotches under the skin a change in the colour of urine passed, blood in the urine | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> a change in the amount or frequency of urine passed, burning feeling when passing urine <p>Other</p> <ul style="list-style-type: none"> hypersensitivity, fever, rash, facial swelling, swollen lymph nodes (which could be symptoms relating to taking Oruvail and associated with raised levels of infection fighting cells (eosinophilia)) a distinctive allergic reaction of the skin known as fixed drug eruption that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching fever, stiff neck, bright lights hurting the eyes, drowsiness or confusion, and nausea and vomiting eye problems such as blurred vision, sore red eyes, itchy eyes, or fluid build up in the eyelids asthma, wheezing, shortness of breath sudden or severe itching, skin rash, hives | |
| <p>Allergic reaction-related:</p> <ul style="list-style-type: none"> swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing hives fainting | <p>Stop taking this medicine and tell your doctor immediately, or go to the Emergency Department at your nearest hospital.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. If you are over 65 years of age you may have an increased chance of getting side effects.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects as follows:

For Australia: Therapeutic Goods Administration online at: www.tga.gov.au/reporting-problems.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Oruvail SR contains

| | |
|---|---|
| Active ingredient (main ingredient) | ketoprofen |
| Other ingredients (inactive ingredients) | colloidal anhydrous silica shellac ethylcellulose purified talc non-pareil beads (PI 1014) (maize starch, sucrose) sodium lauryl sulfate erythrosine titanium dioxide gelatin opacode blue (PI 12300) |

Do not take this medicine if you are allergic to any of these ingredients.

What Oruvail SR looks like

Oruvail SR 200mg - are pink and white capsules, containing white pellets marked with "ORUVAIL SR 200".

The 200mg strength is available in boxes of 28 capsules.

Aust R 42422.

Who distributes Oruvail SR

Oruvail SR is distributed in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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