Oruvail® SR

Ketoprofen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Oruvail SR.

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 taking this medicine against the benefits they expect it will 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 need to read it again.

What Oruvail SR is used for

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.

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

Your doctor, however, may prescribe Oruvail SR for another purpose.

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

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

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

Before you take it

When you must not take it

Do not take Oruvail SR if you have:

- a peptic ulcer (eg a stomach ulcer), a recent history of one, or have had peptic ulcers before
- problems with your heart
- severe kidney or liver disease

Do not take Oruvail SR if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Do not take Oruvail SR if you are in your third trimester of pregnancy.

Do not take Oruvail SR if you are allergic to aspirin or any other anti-inflammatory medicines.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or anti-inflammatory medicines. If you are not sure if you are taking any of these medicines ask your pharmacist.

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 give Oruvail SR to a child or adolescent.

The safety and effectiveness of Oruvail SR in children has not been established.

Do not take it if you are pregnant or intend to become pregnant.
It may affect your developing baby if you take it during pregnancy.

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.

Do not take it after the expiry date (EXP) printed on the pack.
If you take it after the expiry date has passed, it may not work as well.

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

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines including aspirin and other anti-inflammatory 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, 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.

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

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

- 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 skin problems or allergic reactions

Tell your doctor if you 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. This may make you think, mistakenly, that you are better or that it is not serious.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you take Oruvail SR.

Taking other medicines

Tell your doctor or pharmacist 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 each other. These include:

- aspirin, salicylates or other NSAID (anti-inflammatory) medicines
- anticoagulants such as warfarin, and other medicines used to stop blood clots and improve blood flow
- 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. cyclosporin, tacrolimus)
- steroids
- some medicines used to treat depression (eg. SSRIs type)
- some medicines used to treat HIV (eg. tenofovir)
- some contraceptive devices (eg intrauterine devices)

These medicines may be affected by Oruvail SR, 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 taking Oruvail SR.

How to take it

How much to take

The usual dose for this medicine 100mg to 200mg taken once a day.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.
They will tell you exactly how much to take.

Follow the instructions they give you.
If you take the wrong dose, Oruvail SR may not work as well and your problem may not improve.

How to take it

ORUVAIL SR capsules should be taken with plenty of fluids and should be taken with food.

When to take it

Take Oruvail SR at about the same time each day.
Taking your capsules at the same time each day will have the best effect. It will also help you remember when to take the capsules.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Depending on your condition, you may need Oruvail SR for a few days, a few weeks or for longer periods.

Continue taking your medicine for as long as your doctor or pharmacist tells you.

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.

Continue taking the capsules until you finish the pack or until your doctor or pharmacist tells you to stop.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

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 take a double dose to make up for the dose you have missed.

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 when 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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Oruvail SR.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

While you are taking it

Things you must 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.

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

If you get an infection while taking Oruvail SR, tell your doctor.

Oruvail SR may hide the 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.

Things you must 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 to be careful of

Be careful driving or operating machinery 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.

Be careful if you are over 65 and unwell or taking other medicines.

Things that may help your condition

Some self-help measures suggested below 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.

Side effects

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 taking Oruvail SR.

It helps most people with condition, but it may have unwanted side effects in a few people. If you are over 65 years of age you may have an increased chance of getting side effects.

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

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- loss of appetite
- constipation, diarrhoea, pain in the stomach, wind
- ulcers
- dizziness
- drowsiness
- headache
- disorientation
- buzzing or ringing in the ears
- dry or itchy skin
- rash
- sore or dry mouth or tongue
- weight loss

These are mild side effects of this medicine and usually short-lived.

Tell your doctor or pharmacist as soon as possible if you notice any of the following:

- severe pain or tenderness in the stomach
- 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
- fast or irregular heartbeats, also called palpitations
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine

These are serious side effects. You may need medical attention.

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

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- pain or tightness in the chest
- Worsening of heart failure (symptoms of heart failure include shortness of breath, tiring easily after light exercise and swollen ankles & feet).

These may be serious side effects of Oruvail SR. You may need urgent medical attention. Serious side effects are uncommon.

If any of the following happen, stop taking 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 difficultly in swallowing or breathing**
- **hives**
- **fainting**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Oruvail SR. 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.

After taking it

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

Keep your capsules in the pack until it is time to take them.
If you take the capsules out of the box or the blister pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.
Heat and damp can destroy some medicines.

Keep it 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

If your doctor or pharmacist tells you to stop taking Oruvail SR, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it 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.

Ingredients

Active Ingredient:

Oruvail SR 200mg - 200mg ketoprofen per capsule

Inactive Ingredients:

- colloidal anhydrous silica
- shellac
- ethylcellulose
- purified talc
- non-pariel beads (maize starch, sucrose)
- sodium lauryl sulfate
- erythrosine
- titanium dioxide
- gelatin
- opacode blue (PI 12300)

Oruvail SR capsules do not contain gluten, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Oruvail SR is supplied in Australia by:

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Oruvail SR is supplied in New Zealand by:

sanofi-aventis new zealand ltd
56 Cawley St, Ellerslie, Auckland
New Zealand

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