

Orudis[®] Suppositories

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 Orudis Suppositories?

Orudis Suppositories contains the active ingredient ketoprofen. Orudis Suppositories is used to treat the symptoms of rheumatoid arthritis and osteoarthritis.

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

2. What should I know before I use Orudis Suppositories?

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 Orudis Suppositories during the first and second trimester of pregnancy should be avoided, as the safety of Orudis Suppositories 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 Orudis Suppositories?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Orudis Suppositories 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 Orudis Suppositories?

- The usual dose for this medicine is one suppository (100mg) at night.
- Follow the instructions provided and use Orudis Suppositories until your doctor tells you to stop.

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

5. What should I know while using Orudis Suppositories?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using Orudis Suppositories.● 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 Orudis Suppositories
Things you should not do	<ul style="list-style-type: none">● Do not use more than the recommended dose unless your doctor tells you to.● Do not use 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 Orudis

	Suppositories 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 Orudis Suppositories?](#) 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.

Orudis[®] Suppositories

Active ingredient: *Ketoprofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Orudis Suppositories. **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 Orudis Suppositories.**

Where to find information in this leaflet:

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

1. Why am I using Orudis Suppositories?

Orudis Suppositories contains the active ingredient ketoprofen. Orudis Suppositories belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

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

Orudis Suppositories are used to treat the symptoms of rheumatoid arthritis and osteoarthritis. Although Orudis Suppositories can relieve the symptoms of pain and inflammation, it will not cure your condition.

2. What should I know before I use Orudis Suppositories?

Warnings

Do not use Orudis Suppositories 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.

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 use Orudis Suppositories 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 use Orudis Suppositories while you have an infection, Orudis Suppositories 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 Orudis Suppositories 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 use this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

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

It may affect your developing baby if you use it during pregnancy. Like most NSAIDs, Orudis Suppositories 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 use it if you are breastfeeding or planning to breastfeed.

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

Use in children

- Do not give Orudis Suppositories to a child or adolescent.

Orudis Suppositories are 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 Orudis Suppositories 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 Orudis Suppositories.

4. How do I use Orudis Suppositories?

How much to use

- The usual dose for this medicine is one suppository (100mg) at night.

- If required, Orudis capsules may also be taken during the day only as directed by your doctor.
- Follow the instructions provided and use Orudis Suppositories until your doctor tells you to stop.
- The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

How to use it

- Orudis suppositories should be inserted into the back passage at night.

When to use Orudis Suppositories

- Use one Orudis Suppository at night.
- Depending on your condition, you may need Orudis Suppositories for a few days, a few weeks or for longer periods.

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

If you forget to use Orudis Suppositories

Orudis Suppositories should be taken at night.

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

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

If you use too many Orudis Suppositories

If you think that you have used too many Orudis Suppositories, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **Australia 13 11 26** or **New Zealand 0800 POISON** or **0800764766**), 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 Orudis Suppositories?

Things you should do

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking Orudis Suppositories.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Orudis Suppositories.
- 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 Orudis Suppositories.

Orudis Suppositories 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 Orudis Suppositories.

Things you should not do

- Do not use 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 Orudis Suppositories, or lower the dosage, without checking with your doctor or pharmacist.
- Do not stop taking your suppositories 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 Orudis Suppositories 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	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● 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 ● 	

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>	<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"> ● 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 ● a change in the amount or frequency of urine passed, burning feeling when passing urine <p>Other</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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.

New Zealand: Medsafe online at: <https://www.medsafe.govt.nz/safety/report-a-problem.asp>

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 Orudis Suppositories contain

Active ingredient (main ingredient)	ketoprofen
Other ingredients (inactive ingredients)	colloidal anhydrous silica hard fat

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

What Orudis Suppositories looks like

Orudis Suppositories 100mg are white or cream torpedo shaped suppositories.

The 100mg strength is available in packs of 20 suppositories.

Aust R 27531.

Who distributes Orudis Suppositories

Orudis Suppositories are supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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