

# KETORAL

## 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.

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### 1. Why am I using KETORAL?

KETORAL contains the active ingredient ketorolac trometamol. KETORAL is used to relieve pain and reduce inflammation (swelling and soreness) that may occur in the initial period following surgery. For more information, see Section [1. Why am I using KETORAL?](#) in the full CMI.

### 2. What should I know before I use KETORAL?

Do not use KETORAL if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed. Do not use if you have ever had an allergic reaction to any medicine containing ketorolac trometamol, aspirin or any other NSAID medicine, or any of the ingredients listed at the end of the CMI. **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.](#)

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[What should I know before I use KETORAL?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with KETORAL 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 KETORAL?

- Your doctor will decide what dose you will receive depending on your weight, the severity of the pain and your response to the treatment. If you are over 65 years old or have reduced kidney function, your doctor may prescribe a lower dose.

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

### 5. What should I know while using KETORAL?

Things you should do	
	<ul style="list-style-type: none"><li>• Tell your doctor immediately if you become pregnant while taking this medicine.</li><li>• Remind any doctor, dentist or pharmacist you visit that you have</li></ul>

	<p>recently been given KETORAL.</p> <ul style="list-style-type: none"> <li>● Tell your doctor if you get an infection soon after getting KETORAL.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not receive KETORAL for longer than 5 days. Prolonged use may increase the occurrence of side effects.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● Be careful driving or operating machinery until you know how KETORAL affects you.</li> <li>● As with other NSAID medicines, KETORAL may cause dizziness or light-headedness in some people.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● Tell your doctor if you have ever been a heavy alcohol drinker</li> <li>● If you drink alcohol, dizziness or light-headedness may be worse.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>● KETORAL will be stored in the pharmacy or on the ward.</li> </ul>

- It is kept in a cool dry place, protected from light, where the temperature stays below 30°C.

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

## 6. Are there any side effects?

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital: vomiting blood or material that looks like coffee grounds, bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, asthma, wheezing, shortness of breath, sudden or severe itching, skin rash, hives, fainting, seizures or fits, pain or tightness in the chest or palpitations or flu-like symptoms with a rash on the face then an extended rash with a high temperature and enlarged lymph nodes. Tell your doctor or nurse immediately if you notice any of the following: severe pain or tenderness in any part of the stomach or back, severe dizziness, spinning sensation, hearing loss or ringing in the ears, severe or persistent headache, abnormal vision, bleeding or bruising more easily than normal, reddish or purplish blotches under the skin, skin rash, severe blisters and bleeding in the lips, eyes, mouth, nose and genitals, unusual weight gain, swelling of ankles or legs.

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.

# KETORAL

**Active ingredient(s):** *ketorolac trometamol*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using KETORAL. **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 KETORAL.**

**Where to find information in this leaflet:**

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

## 1. Why am I using KETORAL?

**KETORAL contains the active ingredient ketorolac trometamol.** KETORAL belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

**KETORAL is used to relieve pain and reduce inflammation (swelling and soreness) that may occur in the initial period following surgery.**

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

Your doctor may have prescribed it for another reason.

## **2. What should I know before I use KETORAL?**

### **Warnings**

#### **Do not use KETORAL if:**

- you are allergic to ketorolac trometamol, aspirin or any other NSAID medicine, or any of the ingredients listed at the end of this leaflet. Many medicines used to treat headaches, period pain and other aches and pains contain aspirin or are a NSAID medicine. If you are not sure if you are taking any of these medicines, ask your doctor before you are given KETORAL. Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin

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

- you are pregnant or intend to become pregnant.
- you are breastfeeding or intend to breastfeed.
- you have kidney disease

- you have severe liver disease
- you have severe heart failure
- you have recently had or are about to have heart bypass surgery
- you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one or have had peptic ulcers before
- you have or have had any bleeding disorders
- you have asthma
- you suffer from dehydration
- you have nasal polyps syndrome, angioedema or bronchospasm (breathing difficulties)
- you have a history of Stevens-Johnsons Syndrome (a rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals)
- you are receiving the following medicines:
  - other NSAID medicines
  - probenecid, a medicine used to treat gout
  - lithium, a medicine used to treat some types of depression
  - pentoxifylline (oxpentifylline), a medicine used to treat certain blood disorders

**Do not give this medicine to a child under the age of 16 years.**

- Safety and effectiveness in children younger than 16 years have not been established.

## **Check with your doctor if you:**

- you have allergies to any other medicines, foods, preservatives or dyes.
- have had any of the following medical conditions:
  - heartburn, indigestion, stomach ulcers or other stomach problems
  - kidney or liver disease
  - blood disorders
  - skin reactions due to another medicine
  - asthma or breathing disorders
  - a reaction to any other NSAID medicine
  - heart failure
  - high blood pressure or heart problems
  - swelling of the ankles or feet
  - inflammatory bowel disease, such as Crohn's disease
- currently have an infection. KETORAL may hide some of the signs of an infection (e.g. pain, fever) and may make you mistakenly think that the infection is not serious or that you are better.
- plan to have surgery.
- you have ever smoked or been a heavy alcohol drinker.
- take any medicines for any other condition

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**

**You must not be given this medicine if you are pregnant or intend to become pregnant.**

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

KETORAL may impair fertility and is not recommended in women attempting to conceive.

**You must not be given this medicine if you are breastfeeding or intend to breastfeed.**

The active ingredient in KETORAL passes into breast milk and there is a possibility that your baby may be affected

## **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 and KETORAL may interfere with each other. These include:**

- aspirin, salicylates or other NSAID medicines (e.g. ibuprofen, naproxen)

- medicine used to treat some types of depression (e.g. lithium, fluoxetine, paroxetine, citalopram)
- thiothixene, a medicine used to treat psychosis
- alprazolam, a medicine used to treat anxiety
- probenecid, a medicine used to treat gout
- diuretics, also called fluid or water tablets
- medicines used to treat epilepsy (e.g. phenytoin, carbamazepine)
- methotrexate, a medicine used to treat arthritis and some cancers
- warfarin, a medicine used to stop blood clots
- medicines used to treat blood disorders (e.g. pentoxifylline (oxpentifylline), heparin)
- medicines used to treat high blood pressure including ACE inhibitors, angiotensin receptor antagonists and beta-blockers
- certain antibiotics called aminoglycosides

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor has more information on medicines to be careful with or avoid while you are receiving this medicine.

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

## **4. How do I use KETORAL?**

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

- Your doctor will decide what dose you will receive depending on your weight, the severity of the pain and your response to the treatment.
- If you are over 65 years old or have reduced kidney function, your doctor may prescribe a lower dose.

### **How to be given it**

- KETORAL is a sterile, clear, slightly yellow liquid.
- It is given as an injection into a muscle by a doctor or trained nurse.
- It must not be injected directly into the veins (intravenously).

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

- KETORAL should not be given for longer than 5 days.
- Prolonged use may increase the occurrence of side effects.

### **If you use too much KETORAL**

As KETORAL is given to you under the supervision of your doctor or nurse, it is very unlikely that you will receive too much.

**However, if you experience any side effects after being given KETORAL, tell your doctor or nurse immediately.**

Symptoms of overdose may include stomach pain, nausea and vomiting.

## **5. What should I know while using KETORAL?**

### **Things you should do**

#### **Call your doctor straight away if you:**

- become pregnant while taking this medicine
- get an infection soon after getting KETORAL.

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

Tell all doctors, dentists and pharmacists who are treating you that you have recently been given KETORAL.

### **Driving or using machines**

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

As with other NSAID medicines, this medicine may cause dizziness or light-headedness in some people. Make sure you know how you react to this medicine

before you drive a car, operate machinery or do anything else that could be dangerous.

## **Drinking alcohol**

**If you drink alcohol, dizziness or light-headedness may be worse.**

## **Looking after your medicine**

- KETORAL will be stored in the pharmacy or on the ward. It is kept in a cool dry place, protected from light, where the temperature stays below 30°C.

## **6. Are there any side effects?**

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

This medicine helps most people with pain after surgery, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following list of side effects. You may not experience any of them.**

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

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● stomach upset including nausea (feeling sick), heartburn, indigestion</li><li>● pain in the stomach, wind, diarrhoea</li><li>● constipation</li><li>● dizziness, headache</li><li>● drowsiness</li><li>● depression or anxiety</li><li>● insomnia</li><li>● sweating</li><li>● skin rash or hives</li><li>● aching muscles, muscle tenderness or weakness not caused by exercise</li><li>● pain at site of injection</li><li>● dry mouth</li><li>● feeling extremely thirsty</li><li>● passing more or less urine than normal</li></ul>	<p><b>Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.</b></p> <p>This list includes the more common side effects of your medicine. They are usually mild.</p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● severe pain or tenderness in any part of the stomach or back</li><li>● severe dizziness, spinning sensation</li><li>● hearing loss or ringing in the ears</li><li>● severe or persistent headache</li><li>● abnormal vision</li><li>● bleeding or bruising more easily than normal, reddish or purplish blotches under the skin</li><li>● skin rash</li><li>● severe blisters and bleeding in the lips, eyes, mouth, nose and genitals</li><li>● unusual weight gain, swelling of ankles or legs</li></ul>	<p><b>Tell your doctor or nurse immediately if you notice any of these side effects.</b></p> <p>This list includes serious side effects. You may need urgent medical attention. Serious side effects are rare.</p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● vomiting blood or material that looks like coffee grounds</li> <li>● bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea</li> <li>● swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing</li> <li>● asthma, wheezing, shortness of breath</li> <li>● sudden or severe itching, skin rash, hives</li> <li>● fainting, seizures or fits</li> <li>● pain or tightness in the chest or palpitations</li> <li>● flu-like symptoms with a rash on the face then an extended rash with high temperature, increased levels of enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes</li> </ul>	<p><b>Call your doctor or nurse immediately or do straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p> <p>These side effects are rare but may be serious. You may need urgent medical attention or hospitalisation.</p>

## Very serious side effects

**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.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

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

### What KETORAL contains

<b>Active ingredient (main ingredient)</b>	30 mg/mL of ketorolac trometamo
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● ethanol</li><li>● sodium chloride</li><li>● sodium hydroxide or hydrochloric acid</li></ul>

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|  | <ul style="list-style-type: none"><li>• water for injections</li></ul> |
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What KETORAL looks like**

KETORAL is a sterile, clear to slightly yellow solution in a glass syringe. (AUST R 144524).

## **Who distributes KETORAL**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30 – 34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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