

KETORAL

contains the active ingredient ketorolac trometamol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KETORAL.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking KETORAL against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What KETORAL is used for

KETORAL contains ketorolac trometamol as the active ingredient. It belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

KETORAL helps 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.

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

This medicine is not addictive.

Before you take KETORAL

When you must not take it

Do not take KETORAL if you have an allergy to:

- ketorolac trometamol
- aspirin
- any other NSAID medicine
- any of the ingredients listed at the end of this leaflet.

If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines.

Some of the symptoms of an allergic reaction may include

- shortness of breath
- asthma, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- fainting

If you are allergic to aspirin or NSAID medicines and use KETORAL, these symptoms may be severe.

You must not be given KETORAL if you are pregnant, or intend to become pregnant.

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

You must not be given KETORAL if you are breastfeeding or intend to breastfeed.

This medicine passes into breast milk. The effect on the baby is not known.

You must not be given KETORAL if:

- you have kidney disease
- you have severe liver disease

- you have severe heart failure
- 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 dehydration
- you have nasal polyps syndrome, angioedema or bronchospasm (breathing difficulties)
- you have a history of Stevens-Johnson 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
 - oxpentifylline, a medicine used to treat certain blood disorders.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

KETORAL must not be given to children under 16 years of age.

The safety and effectiveness in children under 16 years has not been established.

You must not be given KETORAL for more than 5 days.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you intend to become pregnant.

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

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

- heartburn, indigestion, stomach ulcers or other stomach problems
- kidney or liver disease
- blood disorder
- skin reaction due to another medicine
- asthma or breathing disorders
- a reaction to any other NSAID
- heart failure
- high blood pressure or heart problems
- swelling of the ankles or feet
- inflammatory bowel disease, such as Crohn's disease.

Tell your doctor if you 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.

Tell your doctor if you plan to have surgery.

Tell your doctor if you have ever smoked or been a heavy alcohol drinker.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from a 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 or naproxen)
- medicine used to treat some types of depression (e.g. lithium, fluoxetine, paroxetine or 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. oxpentifylline, heparin)
- medicines used to treat high blood pressure including ACE inhibitors, angiotensin receptor antagonists and beta-blockers
- certain antibiotics called aminoglycosides.

These medicines may be affected by KETORAL or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Ask your doctor if you are not sure about this list of medicines.

How to take KETORAL

How much to take

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 take 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 to take it

KETORAL should not be given for longer than 5 days.

Prolonged use may increase the occurrence of side effects.

If you take too much (overdose)

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.

While you are taking KETORAL

Things you must do

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Tell your doctor if you get an infection soon after getting KETORAL.

KETORAL 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.

Things to be careful of

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

As with other NSAID medicines, KETORAL 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. If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with KETORAL.

This medicine helps most people with pain after surgery but it may have unwanted side effects in some 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.

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

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

- stomach upset including nausea (feeling sick), heartburn, indigestion
- pain in the stomach, wind, diarrhoea
- constipation
- dizziness, headache
- drowsiness
- depression or anxiety
- insomnia
- sweating
- skin rash or hives
- aching muscles, muscle tenderness or weakness not caused by exercise
- pain at site of injection
- dry mouth
- feeling extremely thirsty
- passing more or less urine than normal.

These side effects of KETORAL are usually mild.

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.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor 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.

These side effects are rare but may be serious. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

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

You may not experience any of them.

After taking KETORAL

Storage

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.

Product description

What it looks like

KETORAL is a sterile, clear to slightly yellow solution in a glass syringe.

Available in packs of 5 pre-filled syringes.

Ingredients

KETORAL contains 30 mg/mL of ketorolac trometamol as the active ingredient.

It also contains the following inactive ingredients:

- ethanol
- sodium chloride
- sodium hydroxide or hydrochloric acid
- water for injections

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

Sponsor

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Australian Registration Numbers:

AUST R 144524

This leaflet was prepared on 27 May 2016.

KETORAL_cmi\May16\01