

KETOROLAC APOTEX Solution for Injection

Contains the active ingredient ketorolac trometamol

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully for information on your medicine.

This leaflet answers some common questions about KETOROLAC solution for injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with you. You may want to read it again.

What this medicine is used for

The name of your medicine is KETOROLAC APOTEX solution for injection. It contains the active ingredient ketorolac trometamol.

Ketorolac belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

Ketorolac relieves pain and reduces inflammation (swelling and soreness) that may occur following surgery. Although ketorolac can relieve the symptoms of pain and inflammation, it will not cure your condition.

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

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

There is no evidence that ketorolac is addictive.

Use in children

Do not give ketorolac to a child under 16 years of age.

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

Before you are given this medicine

When you must not be given it

Do not use ketorolac if:

- You have an allergy to:
 - ketorolac or any ingredients listed at the end of this leaflet
 - aspirin or any other NSAID medicineMany medicines used to treat headache, period pain and other aches and pains contains aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.
If you are allergic to aspirin or NSAID medicines and use ketorolac, these symptoms may be severe.
- **You are pregnant or intend to be pregnant.**
Ketorolac may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding or intend to breastfeed.**
Ketorolac may pass into human breast milk.
- **You have or have had any of the following:**
 - kidney disease
 - severe heart failure

- high blood pressure
- a peptic ulcer (stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
- any bleeding disorders
- asthma
- you suffer dehydration
- nasal polyps syndrome, angioedema or bronchospasm (breathing difficulties)
- 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
 - oxpentifylline, a medicine used to treat certain blood disorders
- **You are hypersensitive to, or have had an allergic reaction to, ketorolac or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, tell your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Do not give ketorolac to a child under 16 years of age.

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

Before you are given it

Before you are given this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines

- any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - heartburn, indigestion, stomach ulcers or other stomach problems
 - kidney or liver disease
 - heart failure
 - high blood pressure or heart problems
 - swelling of the ankles or feet
 - inflammatory bowel disease, such as Crohn's disease.
 3. You currently have an infection ketorolac may hide some of the signs of an infection (e.g. pain, fever) and may make you think that the infection is not serious or that you are better.
 4. You intend to become pregnant ketorolac may impair fertility and is not recommended in women attempting to conceive.
 5. You are planning to have surgery.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.
 8. 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 ketorolac.

Some medicines may interact with ketorolac. These include:

- aspirin, salicylates or other NSAID medicines (such as ibuprofen or naproxen)
- warfarin, a medicine used to stop blood clots
- probenecid, a medicine used to treat gout
- oxpentifylline, a medicine used to treat certain blood disorders
- lithium, a medicine used to treat some types of depression

- selective serotonin reuptake inhibitors (SSRIs), medicines used to treat depression (such as fluoxetine, paroxetine or citalopram)
- thiothixene, a medicine used to treat psychosis
- phenytoin, a medicine used to treat epilepsy
- carbamazepine, a medicine used to treat epilepsy
- methotrexate, a medicine used to treat arthritis and some cancers
- heparin, a medicine used to treat blood disorders
- diuretics, also called fluid or water tablets
- medicines used to treat high blood pressure, including ACE inhibitors, angiotensin receptor antagonists and beta-blockers
- certain antibiotics called aminoglycosides

If you are taking any of these you may need a different dose or you may need to take different medicines.

Your doctor will advise you.

Other medicines not listed above may also interact with ketorolac.

How this medicine is given

How much is given

Your doctor will decide what dose of ketorolac you will receive. This depends on your condition.

The usual dose for healthy adults is 10 mg to 30 mg every 4 to 6 hours, up to a maximum daily dose of 90 mg.

If you are over 65 years old or have reduced kidney function, your doctor may prescribe a lower dose.

How it is given

Ketorolac is given as an injection, into a muscle by a doctor or trained nurse.

The injection should not be injected directly into the veins (intravenously).

How long it is given for

Do not receive ketorolac for longer than 5 days.

Prolonged use may increase the occurrence of side effects.

If you receive too much (overdose)

If you think that you or anyone else may have been given too much of this medicine, tell your doctor, or go to the Accident and Emergency department at your nearest hospital.

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

If you receive too much ketorolac, you may have pain or tenderness in the stomach, stomach upset including nausea (feeling sick), vomiting, heartburn or cramps.

If you are not sure what to do, contact your doctor or pharmacist.

While you are being given this medicine

Things you must do

Tell your doctor that you have been given this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant tell your doctor immediately
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital
- if you get an infection soon after receiving ketorolac, tell your doctor.

Ketorolac may hide some of the signs of an infection and may make you

think, mistakenly, that the infection is not serious or that you are better. Signs of an infection may include fever, pain, swelling and redness.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

As with other NSAID medicines, ketorolac may cause dizziness or light-headedness in some people. Make sure you know how you react to ketorolac before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or lightheaded. If this occurs do not drive.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are receiving ketorolac or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- stomach upset including nausea (feeling sick), heartburn, indigestion
- pain in the stomach or wind
- diarrhoea
- dizziness
- drowsiness
- headache
- 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.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- severe pain or tenderness in any part of the stomach or back
- severe dizziness, spinning sensation
- severe or persistent headache
- abnormal vision
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- unusual weight gain, swelling of ankles or legs.

If you experience any of the following, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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 or hives
- fainting, seizures or fits
- pain or tightness in the chest.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to ketorolac tell your doctor immediately or go to the Accident and Emergency

department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

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

Disposal

KETOROLAC solution for injection is used for one dose in one patient only. Any remaining contents should be discarded.

Product description

What KETOROLAC APOTEX Solution for Injection looks like

10 mg/mL and 30 mg/mL solutions for injection are clear and slightly yellow in colour.

Blister pack of 5 ampoules.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each ampoule contains 10 mg/mL KETOROLAC Solution for injection contains 10 mg of ketorolac trometamol.

Each 30 ampoules contain mg/mL KETOROLAC Solution for injection

contains 30 mg of ketorolac trometamol.

It also contains the following inactive ingredients:

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

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

KETOROLAC APOTEX 10 mg/mL solution for injection ampoules: AUST R 217074. KETOROLAC APOTEX 30 mg/mL solution for injection ampoules: AUST R 217079.

Sponsor

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