

# KETOROLAC JUNO

## Solution for Injection

contains the active ingredient ketorolac trometamol

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about KETOROLAC JUNO solution for injection. 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 using KETOROLAC JUNO injection against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What KETOROLAC JUNO is given for

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

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

Your doctor may have prescribed KETOROLAC JUNO for another purpose.

**Ask your doctor if you have any questions why KETOROLAC JUNO has been prescribed for you.**

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

KETOROLAC JUNO is not addictive.

#### Before you are given KETOROLAC JUNO

##### *When you must not use it*

**Do not use KETOROLAC JUNO if:**

**1. you have an allergy to:**

- **KETOROLAC JUNO or any ingredients listed at the end of this leaflet**

• **aspirin or any other NSAID medicine**

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

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting

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

**2. you are pregnant, or intend to become pregnant**

KETOROLAC JUNO may affect your developing baby if you use it during pregnancy.

**3. you are breast-feeding or intend to breast-feed**

KETOROLAC JUNO passes into breast milk. The effect on the baby is not known

**4. you have kidney disease**

**5. you have severe liver disease**

**6. you have severe heart failure**

**7. you have recently had or about to have heart bypass surgery.**

**8. you have a peptic ulcer (stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.**

**9. you have had any bleeding disorders**

**10. you have asthma**

**11. you suffer dehydration**

**12. you have nasal polyps syndrome, angioedema or bronchospasm (breathing difficulties)**

**13. 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).**

**14. 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**

**15. the packaging is torn or shows signs of tampering.**

**16. the expiry date (EXP) printed on the pack has passed.**

If you use this medicine after the expiry date has passed, it may not work as well.

**Do not give KETOROLAC JUNO to a child under 16 years of age.**

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

**If you are not sure if you should be given KETOROLAC JUNO, contact your doctor.**

**Before you are given it**

**Tell your doctor if:**

**1. you have any allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

**2. you intend to become pregnant**

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

If it is necessary for you to be given KETOROLAC JUNO, your doctor will discuss the risks and benefits of receiving it during pregnancy.

**3. 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.

**4. you currently have an infection**

KETOROLAC JUNO may hide some of the signs of an infection (eg pain, fever) and may make you think that the infection is not serious or that you are better.

**5. you plan to have surgery**

**6. 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 JUNO.**

**Taking other medicines**

**Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and KETOROLAC JUNO may interfere with each other. 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
- diuretics, also called fluid or water tablets
- 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
- 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 KETOROLAC JUNO, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

Your doctor and pharmacist has more information on medicines to be careful with or avoid while taking KETOROLAC JUNO.

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

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## How KETOROLAC JUNO is given

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### *How much KETOROLAC JUNO is given*

KETOROLAC JUNO 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).

Your doctor will decide what dose of KETOROLAC JUNO 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.

### *When KETOROLAC JUNO is given*

KETOROLAC JUNO injection is given every 4 to 6 hours as required, up to a maximum daily dose of 90 mg.

### *How long KETOROLAC JUNO is given for*

**Do not receive KETOROLAC JUNO for longer than 5 days.**

Prolonged use may increase the occurrence of side effects.

### *If you receive too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much KETOROLAC JUNO.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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

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

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## While you are receiving KETOROLAC JUNO

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### *Things you must do*

**If you become pregnant while receiving KETOROLAC JUNO, tell your doctor immediately.**

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

**If you are going to have surgery tell your doctor you are being given KETOROLAC JUNO.**

**If you get an infection soon after receiving KETOROLAC JUNO, tell your doctor.** KETOROLAC JUNO 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.

### *Things to be careful of*

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

As with other NSAID medicines, KETOROLAC JUNO may cause dizziness or light-headedness in some people. Make

sure you know how you react to KETOROLAC JUNO before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

### *Storage*

KETOROLAC JUNO will be stored in the pharmacy or on the hospital ward. It is kept in a cool dry place where the temperature stays below 25°C. It should be protected from light.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving KETOROLAC JUNO.**

KETOROLAC JUNO 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 treatment if you get some of the side effects.

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

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

- 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.

These side effects of KETOROLAC JUNO are usually mild.

**Tell your doctor immediately if you notice any of the following:**

- 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
- possible signs of liver problems (nausea, tiredness, itchiness, decreased appetite/weight, pale stools, dark urine, fever, tenderness in the upper abdomen, flu-like symptoms)

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 or hives
- fainting, seizures or fits
- pain or tightness in the chest These are very serious side effects. You may need urgent medical attention or hospitalisation.

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

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.**

**Ask your doctor or pharmacist if you do not understand anything in this list.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## Product Description

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### *What KETOROLAC JUNO looks like*

KETOROLAC JUNO is a clear and colorless to slightly yellow solution in 1 mL glass ampoules.

### *Ingredients*

#### **Active ingredient:**

ketorolac trometamol

Each 30 mg/mL KETOROLAC JUNO solution for injection ampoule contains 30 mg of ketorolac trometamol.

#### **Inactive ingredients:**

- ethanol
- sodium chloride
- sodium hydroxide
- water for injections

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

KETOROLAC JUNO comes in packs of 5 ampoules.

### *Distributor*

KETOROLAC JUNO is sponsored by:

Juno Pharmaceuticals Pty Ltd  
42 Kelso Street,  
Cremorne,  
Victoria 3121

Australian Registration Number AUST R 211626

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