

TORADOL® Injection

contains the active ingredient ketorolac trometamol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TORADOL 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 TORADOL 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 TORADOL is given for

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

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

Your doctor may have prescribed TORADOL for another purpose.

Ask your doctor if you have any questions why TORADOL has been prescribed for you.

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

TORADOL is not addictive.

Before you are given TORADOL

When you must not use it

Do not use TORADOL if:

- 1. you have an allergy to:**
 - TORADOL 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 TORADOL, these symptoms may be severe.

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

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

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

TORADOL 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 are 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 TORADOL 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 TORADOL, 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

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

If it is necessary for you to be given TORADOL, 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

TORADOL 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 TORADOL.

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 TORADOL 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 TORADOL, 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 have more information on medicines to be careful with or avoid while taking TORADOL.

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

How TORADOL is given

How much TORADOL is given

TORADOL 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 TORADOL 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 TORADOL is given

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

How long TORADOL is given for

Do not receive TORADOL 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 TORADOL.

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

You may need urgent medical attention.

If you receive too much TORADOL, 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.

While you are receiving TORADOL

Things you must do

If you become pregnant while receiving TORADOL, tell your doctor immediately.

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

If you are going to have surgery tell your doctor you are being given TORADOL.

If you get an infection soon after receiving TORADOL, tell your doctor.

TORADOL 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 TORADOL affects you.

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

TORADOL 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.

Side Effects

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

TORADOL 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 TORADOL 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

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 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.

Product Description

What TORADOL looks like

TORADOL is a clear to slightly yellow solution in 1 mL glass ampoules.

Ingredients

Active ingredient:

ketorolac trometamol

- each 10 mg/mL TORADOL injection contains 10 mg of ketorolac trometamol
- each 30 mg/mL TORADOL injection contains 30 mg of ketorolac trometamol

Inactive ingredients:

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

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

TORADOL comes in packs of 5 ampoules.

TORADOL is also available as a tablet.

Sponsor

Atnahs Pharma Australia Pty Ltd
Level 10
10 Shelley Street,
SYDNEY, NSW, 2000, Australia

Supplier

TORADOL is supplied in Australia by:

Clinect Pty Ltd
120 - 132 Atlantic Drive
Keysborough VIC 3173
Australia

Customer enquiries: 1 800 899 005

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number

- 10 mg/mL: AUST R 34356
- 30 mg/mL: AUST R 34357

This leaflet was prepared in November 2016.