

# TORADOL® Injection

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## 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.

### 1. Why am I using TORADOL?

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

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

Do not TORADOL if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed. Do not use TORADOL if you are allergic to TORADOL, aspirin or any other NSAID medicine, or any of the ingredients listed at the end of this leaflet.

**Talk to your doctor if you have any other medical conditions or take any other medicines.** For more information, see Section [2. What should I know before I use TORADOL?](#) in the full CMI.

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

Some medicines may interfere with TORADOL 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 TORADOL?

- TORADOL is given as an injection, into a muscle by a doctor or trained nurse. 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. More information can be found in Section [4. How do I use TORADOL?](#) in the full CMI.

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Call your doctor straight away if you become pregnant while receiving TORADOL.</li><li>• Tell your doctor if you get an infection soon after taking TORADOL.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not receive TORADOL for longer than 5 days. Prolonged use may increase the</li></ul>

	occurrence of side effects.
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools until you know how TORADOL affects you.</li> <li>● As with other NSAID medicines, TORADOL 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 drink alcohol.</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>● 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.</li> </ul>

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

## 6. Are there any side effects?

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects: vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions 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, 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 immediately if you notice any of the following serious side effects: severe dizziness, spinning sensation, severe or persistent headache, abnormal vision, bleeding or bruising more easily than normal, reddish or purplish blotches under the skin, severe pain or tenderness in any part of the stomach or back, 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.

# TORADOL<sup>®</sup> Injection

**Active ingredient:** *ketorolac trometamol*

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## Consumer Medicine Information (CMI)

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

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

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

## 1. Why am I using TORADOL?

**TORADOL contains the active ingredient ketorolac trometamol.** TORADOL belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

**TORADOL is used to relieve pain and reduce 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.

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

### **Warnings**

#### **Do not use TORADOL 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 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. If you are allergic to aspirin or NSAID medicines and use TORADOL, these symptoms may be severe. 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

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 (stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
- you 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-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
- **Do not give TORADOL to a child under 16 years of age.**

- The safety and effectiveness in children under 16 have not
- been established.
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- If you are not sure if you should be given TORADOL,
- contact your doctor.

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

- have any other 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
- take any medicines for any other condition
- you have any allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes
- 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.
- you plan to have surgery

- 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.**

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**

**Do not take TORADOL if you are pregnant or intend to become pregnant.**

TORADOL may affect your developing baby if you take it during pregnancy. If it is necessary for you to take TORADOL, your doctor will discuss the risks and benefits of taking it during pregnancy.

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

**Do not take TORADOL if you are breast-feeding or intend to breast-feed.**

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

### 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 may interfere with TORADOL and affect how it works. 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

You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

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

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

### **How 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 use too much TORADOL**

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 think that you have used too much TORADOL, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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

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

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

- become pregnant while receiving TORADOL
- get an infection soon after receiving TORADOL. 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.

Remind any doctor, dentist or pharmacist you visit that you are using TORADOL.

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

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### **Driving or using machines**

**Be careful before you drive or use any machines or tools 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.

## **Drinking alcohol**

### **Tell your doctor if you drink alcohol.**

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

## **Looking after your medicine**

- 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.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Other side effects not listed here may occur in some people. Tell your doctor if you notice anything else that is making you feel unwell.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● <b>Gastrointestinal or gut related:</b></li><li>● stomach upset including nausea (feeling sick), heartburn, indigestion</li><li>● pain in the stomach or wind</li><li>● diarrhoea</li><li>●</li><li>● <b>Head related:</b></li><li>● dizziness</li><li>● drowsiness</li><li>● headache</li><li>● dry mouth</li><li>● feeling extremely thirsty</li><li>● <b>Skin related:</b></li><li>● skin rash or hives</li><li>● sweating</li><li>●</li><li>● <b>Muscle related:</b></li><li>● aching muscles, muscle tenderness or weakness, not caused by exercise</li><li>●</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>● <b>Injection related:</b></li> <li>● pain at site of injection</li> <li>●</li> <li>● <b>Urinary or bladder related:</b></li> <li>● passing more or less urine than normal</li> </ul>	

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>● <b>Head related:</b></li> <li>● severe dizziness, spinning sensation</li> <li>● severe or persistent headache</li> <li>● abnormal vision</li> </ul> <p><b>Bleeding related:</b></p> <ul style="list-style-type: none"> <li>● bleeding or bruising more easily than normal, reddish or purplish blotches under the skin</li> </ul> <p><b>Pain related:</b></p> <ul style="list-style-type: none"> <li>● severe pain or tenderness in any part of the stomach or back</li> </ul>	<p><b>Tell your doctor immediately if you notice any of these side effects. You may need urgent medical attention. These are serious side effects. Serious side effects are rare.</b></p>

Serious side effects	What to do
<p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• unusual weight gain, swelling of ankles or legs</li> </ul>	

## Very serious side effects

Serious side effects	What to do
<p><b>Gastrointestinal or gut related:</b></p> <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>•</li> <li>• <b>Allergic reaction related:</b></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> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● sudden or severe itching, skin rash or hives</li> <li>● fainting, seizures or fits</li> <li>● pain or tightness in the chest</li> <li>● flu-like symptoms with a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.</li> </ul>	

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

### **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.

TORADOL is not addictive.

### What TORADOL contains

<b>Active ingredient (main ingredient)</b>	each 10 mg/mL TORADOL injection contains 10 mg of ketorolac trometamol  each 30 mg/mL TORADOL injection contains 30 mg of ketorolac trometamol
<b>Other ingredients (inactive ingredients)</b>	ethanol  sodium chloride  sodium hydroxide or hydrochloric acid  water for injections
<b>Potential allergens</b>	TORADOL does not contain sucrose, gluten, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What TORADOL looks like**

TORADOL is a clear to slightly yellow solution in 1 mL glass ampoules. TORADOL comes in packs of 5 ampoules.

TORADOL 10 mg/mL injection (AUST R 34356)

TORADOL 30 mg/mL injection (AUST R 34357)

TORADOL is also available as a tablet.

## **Who distributes TORADOL**

TORADOL is supplied in Australia by:

Clinect Pty Ltd

120 - 132 Atlantic Drive

Keysborough VIC 3173

Australia

Customer enquiries: 1 800 899 005

Sponsor:

Atnahs Pharma Australia Pty Ltd

Level 10

10 Shelley Street,

SYDNEY, NSW, 2000, Australia

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