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 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
   - any other NSAID medicines
   - any other medicines, such as foods, preservatives or dyes
   - any other substances, such as foods, preservatives or dyes
   - any other medicines
   - any other substances, such as foods, preservatives or dyes
2. you have kidney disease
3. you have severe liver disease
4. you have severe heart failure
5. you have recently had or are about to have heart bypass surgery
6. you have a peptic ulcer (stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
7. you have had any bleeding disorders
8. you have asthma
9. you suffer dehydration
10. you have nasal polyps syndrome, angioedema or bronchospasm (breathing difficulties)
11. you have a history of Stevens-Johnsons Syndrome (a rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genital)
12. you are undergoing surgery
13. you have had a recent heart attack
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)
- theophylline, 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 you are being given TORADOL.

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

**Even if you are not sure**
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.

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**This leaflet was prepared in November 2016.**

**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**
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

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