

DOLOXENE®

dextropropoxyphene napsylate

Consumer Medicine Information

WARNING: You must not take more than the recommended dose. Even a small overdose of dextropropoxyphene may be fatal. Dextropropoxyphene may result in sudden death if combined with alcohol, antidepressants, tranquilisers or other central nervous system depressants. DOLOXENE is contraindicated in patients with depression or other mental illness and patients who may be at risk of suicidal thoughts. Products containing dextropropoxyphene have been associated with substantial prolongation of the QT interval. DOLOXENE is contraindicated in patients with congenital long QT syndrome or known acquired QT interval prolongation. DOLOXENE is also contraindicated in patients with a history of clinically significant cardiovascular disease, congestive heart failure, cardiac hypertrophy, or arrhythmia. (For other contraindications, see main text.) Elderly patients, and those with renal insufficiency, are also believed to be at higher risk as they are likely to exhibit higher blood levels of dextropropoxyphene and norpropoxyphene. It is **STRONGLY RECOMMENDED that all patients undergoing chronic treatment with dextropropoxyphene products have a renal function blood test and an ECG performed at baseline and periodically (at least every 3 months) to monitor for increased risk. Should patients demonstrate significant renal insufficiency (creatinine clearance below 40 mL/min) and/or ECG results of concern, DOLOXENE MUST be ceased immediately.**

What is in this leaflet

This leaflet answers some common questions about DOLOXENE. It does not contain all the available information and does not take the place of talking with your doctor.

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.

If you have any concerns about taking this medicine or have any questions about the Boxed Warnings, talk to your doctor or pharmacist.

Keep this leaflet with this medicine. You may need to read it again.

Special Prescribing Conditions

Following a decision by the Administrative Appeals Tribunal, additional conditions now apply to the registration of products containing dextropropoxyphene, including DOLOXENE which affect the prescribing and dispensing of these products.

Prescribers are required to complete a prescriber confirmation form when prescribing this medication to a patient. The prescriber confirmation form must be provided to the pharmacist who first dispenses a new prescription. It is not required to be provided to a pharmacist who is dispensing a repeat prescription. Please speak to your prescribing doctor about the details of the new conditions.

What DOLOXENE is used for

DOLOXENE belongs to a group of medicines called analgesics and is used for the relief of mild to moderate pain in patients who do not gain adequate pain relief from other analgesics.

DOLOXENE may be habit forming so it is important to take it exactly as directed by your doctor.

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

Your doctor may have prescribed this medicine for another reason.

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

Before you take it

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take it

Do not take DOLOXENE:

- if you have had an allergic reaction to it or to any other products containing dextropropoxyphene or to any of the ingredients listed at the end of this leaflet (see 'Product Description'). Signs of an allergic reaction include

shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other part of the body; rash, itching or hives on the skin.

- if you have ever had a heart attack, experienced arrhythmia or have any other heart related conditions.
- If you are taking or likely to take alcohol.
- if you have a history of alcoholism or substance abuse.
- if you are over 70 years of age.
- if you have kidney disease.
- if you have liver disease.
- if you have a history of depression or mental illness.
- if you have ever had thoughts of suicide.

Also, do not take DOLOXENE:

- if the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.
- if the packaging is torn or shows signs of tampering or the capsules do not look quite right.

Before you start to take it

You must tell your doctor:

- if you are taking or likely to take alcohol
- if you have heart disease
- if you have or have had kidney or liver disease
- if you have anaemia, a condition in which there is a decreased number of red blood cells
- if you have had any allergies to any other medicines or any other substances, such as foods, preservatives or dyes

Do not take DOLOXENE if you are pregnant or intend to become pregnant unless you and your doctor have discussed the risks and benefits involved.

Do not take DOLOXENE if you are breast-feeding or plan to breast-feed. It is not recommended for use while breastfeeding as it is found in breast milk.

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 may make it unsafe for you to take DOLOXENE, and those other medicines may also be affected by DOLOXENE. These include:

- tranquilisers, medicines that calm you down
- antidepressants, medicines to treat depression
- sedatives, medicines that help you sleep
- orphenadrine, a muscle relaxant
- alcohol

- any other central nervous system depressant drugs
- anticonvulsants eg. carbamazepine
- medicines that prevent blood clotting eg. warfarin.
- medicines that prolong QT interval
- medicines that are CYP3A4 inhibitors
- medicines that predispose hypokalaemia and/or hypomagnesaemia

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

Do not give DOLOXENE to children.

The safety of this medicine in children has not been established.

How to take it

How much to take

Take your medicine as directed by your doctor.

The usual adult dose is one capsule every four hours, as needed for pain relief. The maximum recommended dose is 6 capsules per day. If you are elderly or have a pre-existing kidney or liver condition, you may need to take fewer capsules.

Tell your doctor if you do not get pain relief at the recommended dose.

Do not take more than the recommended dosage even if you are not getting pain relief. DOLOXENE can produce drug dependence when taken in higher than recommended doses. Even a small overdose of dextropropoxyphene may be fatal.

How to take it

Swallow the capsules whole with a glass of water.

When to take it

This medicine can be taken with or without food.

How long to take it

Your doctor will decide how long you should take this medicine.

If you forget to take it

If you forget to take your medicine, take your dose as soon as you remember.

Do not try to make up for missed doses by taking more than one dose at a time.

Do not take more than the dosage recommended by your doctor even if you are not getting pain relief.

Taking more of this medicine may increase the chance of getting an unwanted side effect.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre on 13 11 26, or go to Accident and Emergency at your nearest

hospital, if you think you or anyone else has taken too much DOLOXENE.

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

You may need urgent medical attention.

While you are taking it

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking DOLOXENE.

Tell your doctor if you have chest pain or feel dizzy with shoulder pain.

Tell your doctor or pharmacist before you start any new medicine that you are taking DOLOXENE.

If you become pregnant while you are taking DOLOXENE, tell your doctor or pharmacist.

You should avoid alcohol while you are taking DOLOXENE.

This medicine and alcohol in combination are dangerous and may lead to symptoms of overdose (difficulty breathing, confusion, anxiety, severe drowsiness and dizziness) and sudden death.

Things you must not do

Do not take more than the dosage recommended by your doctor even if you are not getting pain relief.

Do not drive or operate machinery until you know how DOLOXENE affects you.

It may make you drowsy or dizzy.

Do not give DOLOXENE to anyone else.

Side effects

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

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Like other medicines, DOLOXENE may cause some unwanted side effects. These are likely to vary from patient to patient. Some side effects may be related to the dose of DOLOXENE. Your doctor may then decide to adjust the dose you are taking.

Tell your doctor if you notice any of the following common side effects and they worry you:

- dizziness
- sleepiness
- nausea
- vomiting

These side effects may be lessened if you lie down.

Tell your doctor or pharmacist if you notice any of the following less common side effects and they worry you:

- constipation
- stomach pain
- skin rashes
- allergic reactions
- light headedness
- headache
- weakness
- hallucinations
- sensation of extreme happiness, known as euphoria
- abnormal unhappy mood
- minor visual disturbances

- bleeding or bruising more easily than normal
- frequent infections such as fever, severe chills, sore throat or mouth ulcers.

Some of these may be serious side effects of DOLOXENE. You may need medical attention. Serious side effects are rare.

If any of the following happens, stop taking DOLOXENE and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest or heart pain or irregular heart beat
- yellowing of your skin or eyes, known as jaundice
- fits or seizures
- abnormal thought processes and delusions, known as psychoses.

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

After taking it

Storage

Keep your capsules in the blister pack until it is time to take them.

Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking DOLOXENE or you find that this medicine has passed its expiry date, ask your pharmacist what to do with any capsules that are left over.

Product Description

What it looks like

DOLOXENE capsules are pink.

It is available in blister packs of 10 capsules.

Ingredients

Active ingredient:

- dextropropoxyphene napsylate (100 mg).

Inactive ingredients:

- starch-pregelatinised maize
- dimethicone 350.

The capsule shell consists of:

- gelatin
- red iron oxide
- titanium dioxide.

Doloxene does not contain lactose, gluten, sucrose or azo dyes.

Supplier

Aspen Pharmacare Australia Pty Ltd

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Australian Registration Number:
AUST R 161853

This leaflet was revised in February 2014