New Zealand Consumer Medicine Information

DIXARIT®

25 mcg Tablets Clonidine Hydrochloride

What is in this leaflet

This leaflet answers some common questions about DIXARIT tablets. It does not contain all available information. It does not take the place of talking to your doctor or pharmacist. Keep this information with your DIXARIT tablets. You may need to read it again later. This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp and may contain important information about the medicine and its use of which you should be aware.

To find out more about DIXARIT

Ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using DIXARIT.

What DIXARIT is used for

DIXARIT is used to prevent migraine headache and to relieve symptoms of menopausal flushing.

Your doctor may prescribe DIXARIT for other reasons. Ask your doctor if you have any questions about why DIXARIT has been prescribed for you.

Before you take DIXARIT

When you must not take DIXARIT

Only take DIXARIT if it has been prescribed for you by a doctor. Never give it to someone else even if their symptoms seem to be the same as yours. Do not take DIXARIT if you are allergic to clonidine or to any of the other ingredients in DIXARIT. These ingredients are listed in full at the end of this leaflet. If you are uncertain as to whether you have these allergies you should raise those concerns with your doctor. Do not take DIXARIT if you have certain heart problems, such as irregular/slow heart beat.

Do not take DIXARIT after the EXPIRY DATE on the carton or blister strips has passed. Do not take DIXARIT if the packaging is torn or shows signs of tampering.

Before you start to take DIXARIT

Before taking DIXARIT, you must tell your doctor if you have, or have had, any of the following conditions:

- heart failure or any heart or circulation problem
- stroke, or transient ischaemic attack (TIA)
- · mental depression
- sugar diabetes
- constipation

- nerve damage, which may lead to weakness in the arms and legs
- · any problems with your kidneys

If you are not sure if you have, or have had, any of these conditions you should ask your doctor. Before taking DIXARIT it is advisable to tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription. Some medicines and DIXARIT may interfere with each other. These include:

- · other medicines for high blood pressure
- medicines for heart problems
- alcohol
- medicines used to control mood swings and some types of depression

These medicines may be affected by DIXARIT, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do if you are taking DIXARIT with other medicines.

Pregnancy / breastfeeding

Ask for your doctor's advice if you are pregnant, intend to become pregnant, are breastfeeding or intend to breast-feed during your course of medication. Your doctor will discuss the possible risks and benefits of using DIXARIT during pregnancy and breastfeeding. DIXARIT passes into breast milk.

Children

DIXARIT is not recommended for use in children and teenagers up to 18 years of age. Serious side effects have been observed when clonidine, the active ingredient in DIXARIT, is used with methylphenidate in children with ADHD. Therefore, DIXARIT in this combination is not recommended.

Taking DIXARIT

Note: DIXARIT is not suitable for clearing acute migraine headaches nor for the treatment of children under 12 years of age.

Recommended Dose

Your doctor will tell you how much of your medicine you need to take every day. This depends on your condition and whether you are taking other medicines.

For migraine and menopausal flushing the usual starting dose is one tablet two times a day. If necessary your doctor may increase this up to two or three tablets two times a day.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions, ask your doctor or pharmacist for help.

How to take DIXARIT

Take DIXARIT at about the same time each day. DIXARIT should be swallowed with a glass of water.

If you forget to take a dose

It is important to take DIXARIT as directed. If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time. Do not take a double dose of DIXARIT to make up for a dose that you missed.

How long to take DIXARIT

The duration of treatment will depend on your condition. It may take 2-4 weeks until DIXARIT is fully effective. Continue taking DIXARIT for as long as your doctor prescribes it. Ask your doctor or pharmacist if you have any concerns.

Overdose

Seek medical advice if you have taken more than the recommended or prescribed dose of DIXARIT. Advice can be provided by a doctor, pharmacist or Poisons Information Centre (telephone 0800 POISON or 0800 764766).

Signs of overdose may include dryness of mouth, slow heart beat, drowsiness, temporarily stopping breathing and coma. Other signs include dizziness, weakness, lethargy, feeling cold, vomiting, looking pale, or having an irregular heart beat and very occasionally a rise in blood pressure.

While you are taking DIXARIT

Things you must do

Have your blood pressure checked as instructed by your doctor, to make sure DIXARIT is working. If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy when you begin to take DIXARIT or if the dose is increased. This is because your blood pressure is falling suddenly. Standing up slowly will help your body get used to the change in position and blood pressure. The problem usually goes away after the first few days.

Tell your doctor or pharmacist if you begin taking any other medicine while you are taking DIXARIT.

Effects on Ability to Drive or Operate Machinery

You should not drive or operate machinery until you know how DIXARIT affects you. It is possible that DIXARIT may cause dizziness or drowsiness in some people.

Side effects

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of you taking DIXARIT against the expected benefits. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

The more frequently reported side effects of DIXARIT are drowsiness, dryness of the mouth, and light headedness when you stand up suddenly. Less frequently reported side effects of DIXARIT include the following:

blurred vision

- dizziness
- confusion
- nausea and vomiting
- sleep disturbances
- mental depression
- irrational or abnormal thoughts
- irritability
- · decreased sexual drive / impotence
- generally feeling unwell
- thinning of hair
- rash / hives / itching
- constipation
- dryness of the nose and eyes (caution contact lens users)
- pain in the salivary glands
- tingling or numbness of the hands or feet
- larger breasts than normal, in men
- slow or irregular heart beat
- blood glucose increased

Tell your doctor as soon as possible if you experience any side effects during or after taking DIXARIT, so that these may be properly treated. In addition, unexpected effects, not listed above, can occur with any medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after taking DIXARIT.

After taking DIXARIT

Storage

Leave the tablets in the blister strip until it is time to take a dose. The blister strip protects the tablets. Keep your medicine in a cool dry place where the temperature stays below 25°C. Do not store in direct sunlight or heat. Do not leave your medicine in the car or on the window sill.

Keep your DIXARIT where young children cannot reach it.

Disposal

If you have been told by your doctor that you will not be taking DIXARIT anymore, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

Product Description

What is DIXARIT

DIXARIT is the brand name of your medicine. DIXARIT tablets are blue, sugar coated tablets. DIXARIT tablets are available in boxes of 100 tablets.

Ingredients

Each DIXARIT tablet contains 25 micrograms clonidine hydrochloride. The other ingredients are maize starch, colloidal anhydrous silica, povidone, stearic acid, starch, calcium hydrogen phosphate, and lactose.

Manufacturer

DIXARIT tablets are made in Germany and supplied by: BOEHRINGER INGELHEIM (N.Z.) LIMITED PO Box 76-216 Manukau City Auckland Ph 0800 802461

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