

Dixarit® Tablets 25 micrograms



(clonidine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What DIXARIT Tablets are and what they are used for
2. Before you take DIXARIT Tablets
3. How to take DIXARIT Tablets
4. Possible side effects
5. How to store DIXARIT Tablets
6. Further information

1. WHAT DIXARIT TABLETS ARE AND WHAT THEY ARE USED FOR

DIXARIT Tablets contain a medicine called clonidine. This belongs to a group of medicines called vasodilators. Vasodilators widen the blood vessels and this helps the blood to flow more easily.

DIXARIT Tablets are used to prevent migraine attacks and similar types of headache. It is also used to prevent hot flushes that may occur in women during the menopause (change of life).

2. BEFORE YOU TAKE DIXARIT TABLETS

Do not take DIXARIT if:

- You are pregnant, likely to get pregnant or are breast-feeding
- You are allergic (hypersensitive) to clonidine or any of the other ingredients of DIXARIT (see section 6: Further information)
- You have a slow heart rate due to heart problems
- You are already taking other

medicines that contain clonidine. Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using DIXARIT.

Take special care with DIXARIT

Check with your doctor or pharmacist before taking DIXARIT if:

- You have Raynaud's disease (a problem with circulation to the fingers and toes) or other blood circulation problems, including circulation to the brain
- You have heart or kidney problems
- You have or have ever had depression
- You have constipation
- You have a nerve disorder that causes your hands and feet to feel different ('altered sensation')

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking DIXARIT.

As you may get dry eyes whilst taking this medicine, this may be a problem if you wear contact lenses.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because DIXARIT can affect the way some other medicines work. Also some other medicines can affect the way DIXARIT works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines that make you drowsy
 - Medicines for depression such as imipramine or mirtazapine
 - Medicines for severe mental illness such as schizophrenia. These are also known as 'antipsychotics' and include chlorpromazine
 - Beta blockers such as atenolol
 - Water tablets ('diuretics') such as frusemide
 - Alpha blockers such as prazosin or doxazosin. These can also be used for prostate problems in men
 - Vasodilators such as diazoxide or sodium nitroprusside
 - Cardiac glycosides such as digoxin
 - Medicines to lower blood pressure
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking DIXARIT.

Taking DIXARIT with food and drink

You may feel drowsy while taking DIXARIT. Drinking alcohol while taking DIXARIT can make this worse.

Pregnancy and breast-feeding

Do not take DIXARIT if you are pregnant, likely to get pregnant or are breast-feeding.

Driving or using machines

You may feel drowsy, dizzy or could have some disturbances of vision. If affected, you should not drive, operate machinery or take part in any activities where these may put you or others at risk.

Important information about some of the ingredients of DIXARIT

DIXARIT contains lactose and sucrose (types of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE DIXARIT TABLETS

Always take DIXARIT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- The usual starting dose is 50 micrograms (two tablets), two times a day
- If necessary, after two weeks, your doctor may increase the dose to 75 micrograms (three tablets), two times a day

DIXARIT is not recommended for children.

If you take more DIXARIT than you should

If you take more DIXARIT than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you, even if there are no tablets left.

If you forget to take DIXARIT

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking DIXARIT

Do not stop taking DIXARIT without first talking to your doctor.

If you have any further questions on the use of DIXARIT, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DIXARIT can cause side effects, although not everybody gets them.

The side effects described below have been experienced by people taking DIXARIT. They are listed as either very common, common, uncommon, rare or not known.

Very common (affects more than 1 in 10 people)

- Dizziness, feeling tired and more relaxed than usual (sedation)
- Feeling dizzy when you stand up (because your blood pressure has fallen sharply)
- Dry mouth

Common (affects less than 1 in 10 people, more than 1 in 100 people)

- Depression, sleeping problems
- Headache
- Constipation, feeling sick (nausea), pain below the ear (from the salivary gland), being sick (vomiting)
- Erectile dysfunction
- Fatigue

Uncommon (affects less than 1 in 100 people, more than 1 in 1,000 people)

- Problems with understanding what is happening around you, hallucinations, nightmares
- Your hands and feet feeling different ('altered sensation')
- Regular unusually slow heart beat
- Raynaud's phenomenon (a problem with circulation to the fingers and toes)
- Itching, rash, urticaria (nettle rash)
- A feeling of discomfort and fatigue ('malaise')

Rare (affects less than 1 in 1,000 people, more than 1 in 10,000 people)

- Breast growth ('gynaecomastia') in men
- Dry eyes
- Irregular heartbeat
- Drying out of the lining of the nose
- Pseudo-obstruction of the large bowel, which causes colicky pain, vomiting and constipation. Contact your doctor straight away if you have all these side effects.
- Hair loss
- Increase in your blood sugar

Not known

- Confusion, loss of libido
- Blurred vision
- Abnormally slow heart beat

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL – Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. HOW TO STORE DIXARIT TABLETS

Keep out of the reach and sight of children.

The tablets should be stored below 25°C and the blister strips should be kept in the outer carton.

Do not use DIXARIT after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What DIXARIT contains

- The active substance is clonidine hydrochloride. Each tablet contains 25 micrograms.
- The other ingredients are: calcium hydrogen phosphate anhydrous, lactose monohydrate, maize starch, colloidal anhydrous silica, povidone, maize starch soluble, indigo carmine (E132), magnesium stearate, sucrose, talc, acacia, titanium dioxide (E171), macrogol, carnauba wax and white beeswax.

What DIXARIT looks like and contents of the pack

DIXARIT tablets are blue, biconvex, sugar-coated tablets.

DIXARIT tablets are available in blister packs of 112 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for DIXARIT is held by:

Boehringer Ingelheim Limited,
Ellesfield Avenue, Bracknell, Berkshire,
RG12 8YS, United Kingdom

and the tablets are manufactured at:

Delpharm Reims S.A.S.
10 Rue Colonel Charbonneaux,
51100 Reims, France

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