Package leaflet: Information for the patient

Disopyramide Phosphate 150 mg Capsules
Disopyramide Phosphate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

• 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
• If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:
1. What Disopyramide is and what it is used for
2. What you need to know before you take Disopyramide
3. How to take Disopyramide
4. Possible side effects
5. How to store Disopyramide
6. Contents of the pack and other information.

1. What Disopyramide is and what it is used for

Disopyramide belongs to a group of medicines called antiarrhythmic agents. Disopyramide is used to treat an irregularity in the heartbeat (known as an arrhythmia). It works by correcting irregular heartbeats to a normal rhythm.
It is used for controlling your heartbeat in the following situations:
• Arrhythmias - where your heartbeats are uneven, or unusually fast or slow.
• To keep your heart beating at a normal rhythm.
• To stop unusual heartbeats (arrhythmias) happening after a heart attack.
• To stop unusual heartbeats (arrhythmias) during an operation.

2. What you need to know before you take Disopyramide

Do not take Disopyramide if you:
• are allergic (hypersensitive) to disopyramide phosphate or any of the other ingredients of this medicine (listed in section 6)
• have been told by your doctor you have other heart problems apart from unusual heartbeats e.g. heart block or heart failure
• are already taking any other medicine to regulate your heartbeat.

Warnings and precautions
Talk to your doctor or pharmacist before taking Disopyramide if you:
• have a kidney or liver disease
• have low levels of potassium in your blood (hypokalaemia)
• have low blood sugar levels. This can happen if you have diabetes, a low body weight, a poor diet or if you are elderly
• have an enlarged prostate
• suffer from glaucoma (increased eye pressure)
• suffer from a disease which causes muscle weakness (myasthenia gravis)
• are elderly and have problems with your memory or attention span or sometimes have difficulty thinking clearly.
• suffer from heart disease or any other heart condition.

Other medicines and Disopyramide
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, or the following:
• antibiotics e.g. erythromycin, quinupristin, dalfopristin, rifampicin, clarithromycin, amphotericin, pentamidine, sparfloxacin
• antivirals e.g. ritonavir, indinavir, saquinavir
• an anti-malarial halofantrine
• anticholinergics, to relieve stomach cramps or spasm, to prevent travel sickness and to treat Parkinson's disease e.g. atropine
• beta-blockers to treat a heart condition e.g. atenolol, sotalol, propranolol, or other anti-arrhythmics e.g. digoxin, verapamil, amiodarone, procainamide, lidocaine (See Section 'Do not take' above)
• diuretics ('water' tablet) e.g. frusemide, bendrofluazide
• a medicine used to treat glaucoma acetazolamide
• antidepressants e.g. amitriptyline, imipramine or maprotilene,
• anti-epileptics e.g. phenytoin, phenobarbital, primidone
• anticoagulants e.g. warfarin
• laxatives to treat constipation
• antihistamines terfenadine, mizolastine, astemizole
• an anti-nausea medicine tropisetron
• medicines used to help develop or maintain an erection e.g. sildenafil
• pimozide, sertindole and thioridazine (used for schizophrenia), cisapride (used for heartburn), ciclosporin (used to help prevent rejection of transplants), theophylline (used for wheezing or difficulty in breathing), corticosteroids or tetracosactrin (tetracosactide).

During treatment with Disopyramide
Talk to your doctor or pharmacist if you suffer from a worsening of myasthenia gravis (a disease which causes muscle weakness).

Pregnancy and breast-feeding – If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking this medicine. This is because small amounts of disopyramide can pass into breast milk.

Driving and using machines - Do not drive or operate machinery if you feel dizzy or drowsy, or you have problems with your vision while taking this medicine.

Disopyramide contains lactose. If your doctor has told you that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

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

Your doctor will choose the dose which best suits your condition. Swallow the capsules whole with a glass of water.
Do not chew or open the capsules.

**Adults** – The recommended dose is between 300 mg and 800 mg. This should be taken divided up into doses spaced evenly through the day.

**Patients with liver or kidney problems** - Your doctor may give you a lower dose and will closely monitor you.

**Elderly** - If you are elderly, your doctor may prescribe a lower starting dose for you.

**Children** - Disopyramide is not recommended for use in children.

**If you take more Disopyramide than you should** - Contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining capsules with you. You may get the following side effects: dizziness, feeling tired, uneven heartbeat, dry mouth, difficulty passing urine, feeling or being sick, stomach pain or fits.

**If you forget to take Disopyramide** - Take the next dose as soon as you remember unless it is less than 4 hours before for your next dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Disopyramide** – If you suddenly stop taking Disopyramide you may experience side effects. Speak to your doctor first before stopping this medicine.

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

### 4. Possible side effects

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

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- if you have an allergic reaction. The signs may include a skin rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell your doctor as soon as possible if you have any of the following side effects:

- feeling faint, dizzy or light-headed,
- palpitations or an uneven, fast or slow heartbeat that you have not had before or that gets worse.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet:

- blurred or double vision,
- pain when urinating or difficulty urinating, especially in men with prostate problems,
- stomach pain, feeling sick (nausea) or being sick (vomiting), constipation or diarrhoea, loss of appetite, dry mouth,
- difficulty in getting or maintaining an erection, or in ejaculating (impotence),
- mood changes or mental problems,
- problems with memory or attention span, difficulty thinking clearly,
- skin reactions: red spots on your skin called rashes may appear very rarely.

Rarely:
• a fall in blood sugar level (hypoglycaemia), this may make you have chills and cold sweats, look pale, feel confused or anxious and unusually tired or weak.

Very Rarely:
• yellowing of the skin or whites of the eyes (jaundice),
• headache,
• lightheadedness feeling,
• you may get more infections than usual. This could be caused by a lowering in the number of white blood cells in your blood (neutropenia).

Rapid infusion may lead to experience abundant sweats.

**Reporting of side effects**
If you get any side effects talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Disopyramide**

Keep out of the sight and reach of children. Store in a dry place below 25°C. Do not use Disopyramide after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information**

**What Disopyramide contains** – The active substance is disopyramide phosphate. The other ingredients are lactose, maize starch, povidone, talc and magnesium stearate. The capsule shell includes gelatin, red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171). The printing ink contains shellac, propylene glycol, iron oxide black (E172) and ammonium hydroxide.

**What Disopyramide looks like and contents of the pack** - Your medicine comes as a buff coloured capsule. Disopyramide is available in blisters or plastic bottles of 28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 500 or 1000 capsules. Not all pack sizes may be marketed.

**Marketing Authorisation Holder** -
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

**Manufacturer** –
Gerard Laboratories, Unit 35, Baldoyle Industrial Estate, Grange Road, Dublin 13, Eire.

**The leaflet was last revised in 10/2016**