

## What you should know about ADIZEM<sup>®</sup>-XL capsules

### Diltiazem Hydrochloride PhEur

Please read this leaflet before you start taking your capsules.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Keep this leaflet in a safe place - you may want to read it again.

#### What is in the capsules?

The capsules contain the active ingredient diltiazem hydrochloride (120 mg, 180 mg, 240 mg or 300 mg).

The capsules also contain the following inactive ingredients:

- |                              |                           |
|------------------------------|---------------------------|
| * Microcrystalline cellulose | * Ethylcellulose          |
| * Colloidal anhydrous silica | * Polysorbate             |
| * Dibutyl sebacate           | * Magnesium stearate      |
| * Gelatin                    | * Sodium dodecylsulphate  |
| * Indigo carmine (E132)      | * Titanium dioxide (E171) |
| * Iron oxide (E172)          | * Erythrosine (E127)      |

The 300 mg capsule also contains patent blue V (E131).

The capsules are printed with ink containing shellac, soya lecithin, 2-ethoxyethanol, dimethicone, and titanium dioxide (E171).

In each box there are 4 or 28 capsules.

Diltiazem belongs to a group of medicines called calcium antagonists. They help more blood to reach the heart. They also reduce blood pressure.

The capsules are made by Bard Pharmaceuticals for the authorisation holder Napp Pharmaceuticals Ltd, both at the Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

#### What are the capsules for?

The capsules are used to treat angina and hypertension (high blood pressure). If you would like to know about angina and hypertension, please read the section at the end of this leaflet.

#### Who can take the capsules?

Adults can take the capsules. They are not recommended for children.

Before you take the capsules, please tell your doctor or pharmacist, if:

- \* you are pregnant or breast feeding,
- \* you are a woman of child bearing age,
- \* you are taking any other medicines for angina or hypertension,
- \* you are taking anti-arrhythmic drugs (drugs to treat an irregular or rapid heart beat),
- \* you are taking medicines for stomach ulcers,
- \* you are receiving dantrolene, digoxin, cyclosporin, carbamazepine or theophylline.

Also tell your doctor or pharmacist if you have any condition in the list below:

- \* Slow heart beat
- \* Heart problems, other than angina or hypertension
- \* Porphyria (a rare disease of blood pigments)
- \* You are allergic to any of the capsule ingredients

If you are going to have an operation or a liver function test, please tell the doctor that you are taking these capsules.

Only take the capsules if they have been prescribed for **you**. Never give them to other people, even if their symptoms are the same as yours.

#### How do I take my capsules?

The label on your medicine will tell you how many capsules to take and how often. If you are not sure, ask your doctor or pharmacist.

Swallow your capsules whole with water. **Don't** crush or chew them.

The usual starting dose is one 240 mg capsule daily for adults and one 120 mg capsule daily for the elderly. Your doctor may prescribe a different dose to this. You may want to discuss this with your doctor.

You should take your capsules at the same time every day. For instance, if you take a capsule at 8 o'clock in the morning, you should take your next capsule at 8 o'clock the next morning.

It is important that you do not stop taking your medicine, even if you feel better, without talking to your doctor first.

### **What should I do if I forget to take my capsules?**

If you forget to take your capsules, take your next dose as soon as you remember, unless it is almost time for your next dose. Then go on as before.

### **What should I do if someone accidentally swallows my capsules or I take too many?**

Contact your doctor or local hospital straight away.

### **Will I have any problems?**

Most people will not have any problems when taking these capsules.

Problems that do occur are usually mild and wear off after the treatment is stopped. These problems include feeling sick, tired or dizzy, having a headache, flushing or swollen legs. Rarely, patients may experience constipation or diarrhoea, low blood pressure, heart problems other than angina or hypertension, or hepatitis.

In rare cases, skin reactions may occur. These include exfoliative dermatitis (flaking skin), angio-oedema (swollen skin), erythema multiforme (red, swollen skin), and vasculitis (inflammation of the blood vessels). Another rare reaction is gingival hyperplasia (overgrowth of the gums).

If any of these trouble you or you have any other problems, please tell your doctor.

### **How should I keep my capsules?**

There is a 'use-by' date on the box. For example, EXP 8.2005 means that you should not take the capsules after the end of August 2005. After the 'use-by' date, take your capsules to a pharmacy.

Do not keep your capsules above 25°C (77°F). Keep them in a safe place where children cannot see or reach them.

### **Date this leaflet was written:-**

March 2000

### **What are angina and hypertension?**

Angina is chest pain caused by a reduction of oxygen to the heart muscle. It usually occurs, for example, during exercise and at times of stress.

Hypertension is also called high blood pressure.