Digoxin 62.5micrograms, 125micrograms and 250micrograms tablets PIL UK

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

- Keep this leaflet. You may need to read it again.
- 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 you have any questions, ask your doctor or pharmacist.
- If you have any of the side effects, or if you notice any not listed, please tell your doctor or pharmacist.

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1. What Digoxin tablets are and what they are used for
Digoxin belongs to a group of medicines called cardiac glycosides, these slow down the rate of the heart but increase the force with which the heart muscle contracts, making the heart work more efficiently.

Digoxin tablets are used to treat:
- heart failure.
- irregular heart beats or heart rhythm.

2. Before you take Digoxin tablets
Do not take Digoxin tablets if you:
- are allergic (hypersensitive) to Digoxin tablets, other related medicines such as digitoxin, or any of the ingredients in the tablet (see section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue. If this is the first time your doctor has prescribed this medicine for you, tell them if you have taken any cardiac glycoside (such as digoxin, digitoxin) within the last two weeks.
- have any serious heart problems such as inflammation of the heart, enlargement of the heart muscle, problems in conduction of the electrical impulses in the heart or irregular heart beats including Wolff Parkinson White syndrome. Although digoxin is used to treat serious heart problems, it may make others worse.

Check with your doctor or pharmacist before taking Digoxin tablets if you:
- have any serious lung or breathing disorders
- have been told you have a low blood potassium or magnesium level, or a high blood calcium level
- have suffered a recent heart attack
- have any stomach or bowel problems
- suffer from abnormal heart rhythm
- have congestive heart failure.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:
- the herbal remedy St Johns Wort (Hypericum perforatum) this should not be taken at the same time as digoxin. Consult your doctor before you stop taking St Johns Wort.
- telmisartan, prazosin, captopril, nefopamine, nisoldipine, verapamil, diltiazem, nitropresside, hydralazine, acetazolamide, furosemide, triamterene, spironolactone, or amiloride (used to treat high blood pressure)
- sulfasalazine, penicillamine, chloroquine or hydroxychloroquine (used to treat rheumatoid arthritis)
- anastrozole, colestipol, fluvastatin, niacin, propafenone, or quinidine (used to treat irregular heart rhythms), beta blockers (e.g. propranolol or atenolol) used to treat various heart conditions
- tetracycline, azithromycin, clarithromycin, erythromycin, telithromycin, metronidazole, tetracyclines (used to treat infections caused by bacteria) or amphotericin, itraconazole (used to treat infections caused by fungi)
- nefazodone, trazodone or lithium (used to treat depression) and alprazolam or diazepam (used to treat anxiety)
- acarbose (used to treat diabetes)
- phenytoin, topiramate (used to treat epilepsy)
- quinine (used to treat malaria and night-time leg cramps)
- calcium salts (e.g. calcium carbonate or calcium lactate) and vitamin D
- carbamazepine (used to treat hyperthyroidism)
- ciclosporin (used following organ transplants)
- corticosteroids (e.g prednisolone, hydrocortisone)
- medicines used to treat cancer
- ephedrine, pseudoephedrine, ephedrine sulphate, or ephedrine (muscle relaxants)
- aspirin, azapropazone, diclofenac, fenbufen, ibuprofen, indometacin, ibuprofen, lornoxicam, naproxen, or phenylbutazone (medicines known as Non-Steroidal Anti-inflammatory Drugs (NSAIDs) and used to treat pain)
- salbutamol (used to treat asthma)
- carbenoxolone, omeprazole, pantoprazole, rabeprazole, or sucralfate (used to treat stomach ulcers)

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### 3. How to take Digoxin tablets

Always take Digoxin tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets whole with water at the same time each day. Take this medicine for as long as your doctor tells you to as it may be dangerous to stop without their advice.

The first time you take Digoxin tablets, your doctor will ask you to take a certain number of tablets as a single dose, this is called the initial dose. They will monitor your response which may involve a blood test.

This initial dose is followed by a maintenance daily dose. This might be a different number of tablets depending on how you respond. Your doctor might recommend that you take this maintenance dose in divided doses.

The usual doses are:

- **Adults and children over 10 years:** Initial dose is either between 750 micrograms and 1500 micrograms as a single dose or 250 micrograms and 750 micrograms once a day for 7 days depending on how quickly your doctor wants you to start the tablets. This is then followed by a maintenance dose, which is usually 125 micrograms to 200 micrograms daily.

- **Children under 10 years:** Initial dose is between 25 and 45 micrograms per kg of bodyweight over a 24 hour period (this will depend on the child's age). Depending on the child's response the doctor will decide upon the best maintenance dose.

Elderly or patients with kidney, thyroid or bowel disorders: different doses will be given depending on the condition.

If you take more Digoxin tablets than you should

If you (or someone else) swallow a lot of the tablets all together, or if you (or someone else) swallow a lot of the tablets at the same time each day, this is called the initial dose. They will monitor your response which may involve a blood test.

If you forget to take Digoxin tablets

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Take the remaining doses at the correct time. If you are worried ask your pharmacist or doctor for advice.

### 4. Possible side effects

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

- **Stop taking** the tablets and **tell your doctor immediately** or contact the casualty department at your nearest hospital if the following allergic reaction occurs: skin rash, which might be itchy and/or red and swelling of the mouth, tongue and throat causing difficulty swallowing or breathing. This is a very rare but serious side effect, you may need urgent medical attention or hospitalisation.

- **Tell your doctor** if you notice any of the following side effects or others not listed:

  - **Effects on blood:** changes in the number and type of certain blood cells. If you notice unusual bruising, nose bleeds or infections you should tell your doctor.
  - **Effects on hormones:** swelling of the breasts in men.
  - **Effects on mental health:** disorientation, confusion, forgetfulness, delirium, psychosis, depression, hearing or seeing things that are not there and fits.
  - **Effects on the nervous system:** headache, fatigue, weakness, dizziness, sleepiness, bad dreams, restlessness, nervousness, agitation and lack of interest in everyday life.
  - **Effects on the eyes:** blurred vision, intolerance to light, colour vision may be affected with objects appearing yellow, or less frequently, green, red, blue, brown or white.
  - **Effects on the heart:** irregular or fast heartbeats or heart failure (new or worsening of an old condition).
  - **Effects on the stomach and intestines:** loss of appetite, feeling or being sick. Diarrhoea and abdominal pain particularly in the elderly.

**Side-effects in children:**

Children are especially sensitive to the effects of digoxin. Side-effects may include loss of appetite, feeling or being sick and diarrhoea. Irregular or fast heartbeats have been reported.

**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 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 Digoxin tablets

Keep out of the sight and reach of children.

Store below 25°C in a dry place, and in the original packaging.

Do not use Digoxin tablets after the expiry date stated on the label/carton/ bottle. 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 to protect the environment.

### 6. Further information

**What Digoxin tablets contain**

- The active substance (the ingredient that makes the tablets work) is digoxin. Each tablet contains either 62.5 microgram (blue uncoated tablet), 125 microgram & 250 microgram (white uncoated tablets) of the active ingredient.

- The other ingredients are lactose, magnesium stearate, maize starch and pregelatinised maize starch (all 3 strengths), stearic acid (250 microgram only), indigo carmine (E132) (62.5 microgram only).

### Contents of the pack

Digoxin tablets are available in pack size of 28

**Marketing Authorisation holder and manufacturer**

Actavis, Barnstaple, EX32 8NS, UK

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