

PACKAGE LEAFLET: INFORMATION FOR THE USER

CARDEXIN 0.25

(DIGOXIN TABLETS BP 0.25 mg)

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, please ask your doctor or pharmacist or nurse.
- 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 get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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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 heartbeats 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 heartbeats 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 or heart problems such as cardiac amyloidosis, myocarditis, constrictive pericarditis
- have Beri-beri disease
- are going to have a heart test called an ECG (electrocardiogram)
- have a thyroid disease
- have malabsorption syndrome
- have a sinoatrial disorder, e.g. Sick Sinus Syndrome.

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*)
- Medicines to treat high blood pressure (epoprostenol, carvedilol, telmisartan, prazosin, captopril, nifedipine, nisoldipine, verapamil, diltiazem, nitroprusside, hydralazine, acetazolamide, furosemide, triamterene, spironolactone, amiloride)
- Medicines to treat irregular heart rhythms (dronedarone, amiodarone, disopyramide, flecainide, moracizine, propafenone, quinidine)
- Medicines to treat heart conditions (milronine, beta blockers; propranolol or atenolol)
- Ranolazine (to treat angina)

- Medicines treating allergic reactions/shock/heart attack (adrenaline/epinephrine, noradrenaline/norepinephrine, atropine, dobutamine)
- Ticagrelor (to prevent blood clots)
- Medicines to lower cholesterol (atorvastatin, colestipol, colestyramine)
- Medicines to treat arthritis (sulfasalazine, penicillamine, chloroquine, hydroxychloroquine)
- Kaolin (for stomach upsets), laxatives (for constipation), metoclopramide (to treat feeling and being sick), antacids (for indigestion)
- Medicines to treat bacterial infections (tetracycline, gentamicin, azithromycin, clarithromycin, erythromycin, telithromycin, neomycin, rifampicin, trimethoprim) or fungal infections (amphotericin, itraconazole, ketoconazole)
- Medicines to treat HIV (atazanavir, darunavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir)
- Taleprevir (to treat hepatitis C)
- Nefazodone, trazodone, lithium (for depression), alprazolam, diazepam (for anxiety)
- Acarbose (for diabetes)
- Phenytoin, topiramate (for epilepsy)
- Quinine (to treat malaria or night-time leg cramps)
- Calcium salts (calcium gluconate or calcium lactate), vitamin D
- Carbimazole (for hyperthyroidism)
- Cyclosporine (to reduce organ transplant rejection)
- Corticosteroids (prednisolone, hydrocortisone)
- Medicines used to treat cancer (lapatinib)
- Propantheline, edrophonium, suxamethonium, pancuronium, or tizanidine (muscle relaxants)
- Medicines known as Non-Steroidal Anti-inflammatory Drugs (NSAIDs) used to treat pain (aspirin, azapropazone, diclofenac, fenbufen, ibuprofen, indometacin, tiaprofenic acid, phenylbutazone)
- Salbutamol (for asthma)
- Carbenoxolone, omeprazole, pantoprazole, rabeprazole, sucralfate (for stomach ulcers)
- Tolvaptan, conivaptan (used in kidney disease)
- Bupropion (to aid stopping smoking)
- Nutritional supplements feed into the body through a tube

Sugar intolerance

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine as it contains lactose.

Pregnancy and breastfeeding

If you are pregnant, plan to become pregnant or are breast feeding speak to your doctor before taking this medicine.

Driving and using machines

Digoxin tablets may make you feel drowsy, dizzy, and affect your vision. Make sure you are not affected before you drive or operate machinery.

Other treatment or surgery

If you need an operation or other treatment, make sure you tell the doctor you are taking digoxin.

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 750micrograms and 1500micrograms as a single dose or 250micrograms and 750micrograms 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 125micrograms to 250micrograms daily.

Children under 10 years: Initial dose is between 25 and 45micrograms 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 your should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department, or your doctor, immediately. Take any remaining tablets and the container with you to give to the doctor.

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 occurs:

- Allergic reaction: skin rash, which might be itchy and/or red and swelling of the mouth, tongue and throat causing difficulty swallowing or breathing
- Palpitations, chest pain, shortness of breath or sweating. These can be symptoms of a serious heart problem caused by new irregular heartbeats

Other side effects may include:

Common (may affect up to 1 in 10 people)

- Rash, urticaria
- Abnormal heartbeat
- Nausea, vomiting, diarrhoea
- Central nervous system disturbances such as dizziness
- Visual disturbances

Uncommon (may affect up to 1 in 100 people)

- Depression

Rare (may affect up to 1 in 1,000 people)

- Changes in the number and type of certain blood cells. If you notice unusual bruising, nose bleeds or infections you should tell your doctor

Very rare (may affect up to 1 in 10,000 people)

- Decrease in blood platelets (symptoms include bruises and nose bleeds)
- Loss of appetite (anorexia)
- Psychosis, apathy, confusion
- Headache
- Stomach pain caused by lack of blood supply or damage to your intestines (ischaemia and necrosis)
- Enlarged breast tissue in men (gynaecomastia)
- Lack of energy (fatigue), a general feeling of being unwell and weakness

Not known (Cannot be estimated from the available data)

- Disorientation, forgetfulness, delirium, hearing or seeing things that are not there, fits
- Fatigue, weakness, sleepiness, bad dreams, restlessness, nervousness, agitation and lack of interest in everyday life
- Blurred vision, intolerance to light, colour vision may be affected with objects appearing yellow, or less frequently, green, red, blue, brown or white
- Heart failure (new or worsening of an old condition)
- Abdominal pain

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.

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 30°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 Digoxin BP 0.25 mg of the active ingredient.
- The other ingredients are Lactose, Polyvinyl Pyrollidone, Sodium propyl paraben, Isopropyl Alcohol, Methylene Chloride, Croscarmellose Sodium, Magnesium Stearate and Maize Starch.

Contents of the pack

Blister pack of Printed Alu foil & Clear PVC Film.

Marketing Authorisation holder and manufacturer

Bliss GVS Pharma Ltd.

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