

Package leaflet: Information for the patient

Digoxin 62.5micrograms, 125micrograms and 250micrograms tablets

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. See section 4.

What is in this leaflet:

- 1 What Digoxin tablets are and what they are used for**
- 2 What you need to know before you take Digoxin tablets**
- 3 How to take Digoxin tablets**
- 4 Possible side effects**
- 5 How to store Digoxin tablets**
- 6 Contents of the pack and other information**

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 What you need to know before you take Digoxin tablets

Do not take Digoxin tablets if you:

- are **allergic** to digoxin, other cardiac glycosides or any of the other ingredients of this medicine (listed in section 6)
- have **serious heart problems**, such as those with the conduction of the electrical impulses in the heart, especially if you have a history of Stokes-Adams attacks (abrupt, short-lived loss of consciousness caused by a sudden change in heart rate or rhythm)
- have an **irregular heart-beat** caused by cardiac glycoside intoxication or conditions such as **Wolff-Parkinson-White syndrome**
- have **obstructive cardiomyopathy** (enlargement of the heart muscle).

Warnings and precautions

Talk to your doctor or pharmacist before taking Digoxin tablets if you:

- are taking this medicine, your doctor may ask you to have regular blood tests to determine the amount of digoxin in the blood. This may be useful in the case of patients with kidney disorders.
- develop digoxin toxicity, this can lead to various forms of heart rhythm disturbances, some of which resemble the rhythm disturbances for which the product was prescribed.
- have abnormal heart rhythm (heart block) and you are taking this medicine, contact your doctor immediately if you feel one or more of the following symptoms: fainting, short-lasting loss of consciousness, dizziness or light-headedness, fatigue (tiredness), shortness of breath, chest pain, irregular heart-beat or confusion.
- have a sinoatrial disorder (a disorder in the conduction of electrical impulses in the heart such as Sick Sinus Syndrome), in some patients with a sinoatrial disorder this medicine can cause a slow and/or irregular heartbeat. Sometimes this will cause tiredness, weakness and dizziness and when your heartbeat is very slow you may faint.

- have recently suffered a heart attack.
- when heart failure occurs along with the collection of an abnormal protein in the heart tissue (cardiac amyloidosis), an alternative therapy may be prescribed by the doctor.
- have myocarditis (inflammation of the heart muscle) this may cause vasoconstriction (narrowing of the blood vessels) on rare occasions. Your doctor may prescribe you a different medicine.
- have Beri-beri disease (caused by a vitamin B1 deficiency).
- have constrictive pericarditis (inflammation of the sac which contains the heart).
- are taking diuretics (drugs which promote urine production and help reduce the amount of water in your body) with or without an ACE inhibitor (mainly used to treat high blood pressure), your doctor will prescribe a lower dose of Digoxin tablets. Do not stop taking Digoxin tablets without talking to your doctor.
- have a heart test called an ECG (electrocardiogram), tell the person doing the test that you are taking Digoxin tablets as it can affect the meaning of the results.
- have severe respiratory (lung) disease (as you may have an increased sensitivity to digoxin).
- have low levels of oxygen reaching certain parts of your body, low levels of potassium, abnormally low levels of magnesium or increased levels of calcium in your blood
- have thyroid disease (such as an under-active or over-active thyroid) as you might require changes in the dose of this medicine.
- have malabsorption syndrome (you cannot absorb minerals from your food properly) or if you have ever had gastrointestinal reconstruction surgery.
- will receive electric shock treatment to correct an abnormal heartbeat.

Other medicines and Digoxin tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Taking several medicines can sometimes have harmful consequences or lead to unwanted interactions. Sensitivity to digoxin can be increased by medicines which lower the level of potassium in the blood.

These include:

- diuretics
- lithium salts (antidepressants)
- corticosteroid based products
- carbenoxolone (a product which strengthens the gastric mucosa).

The following medicines increase the level of digoxin in the blood, which can increase the risk of toxicity:

- certain products which affect the heart: amiodarone, flecainide, prazosin, propafenone
- quinidine
- canagliflozin (used to treat of type 2 diabetes mellitus)
- certain antibiotics: erythromycin, clarithromycin, tetracycline, gentamicin, trimethoprim

- daclatasvir, simeprevir, velpatasvir (used in combination with other medications to treat hepatitis C)
- flibanserin (used to treat low sexual desire in women who have not gone through menopause)
- isavuconazole, itraconazole (used to treat fungal infections)
- ivacaftor (used to treat cystic fibrosis)
- spironolactone (a drug which increases the amount of urine you produce)
- alprazolam (a sedative which may be used to treat anxiety)
- indomethacin (used to treat inflammation)
- quinine (may be used to prevent malaria infection)
- propantheline (used to prevent muscle spasms)
- mirabegron (used to treat overactive bladder that causes a sudden urge to urinate resulting in involuntary loss of urine)
- nefazodone (an antidepressant)
- atorvastatin (lowers blood cholesterol)
- cyclosporin (an immunosuppressant often used to prevent transplant rejection)
- epoprostenol (used to treat pulmonary arterial hypertension)
- tolvaptan, conivaptan (used to treat low blood sodium levels)
- carvedilol (used to treat mild to severe congestive heart failure and high blood pressure)
- ritonavir (used to treat HIV infection and AIDS)
- telaprevir (used to treat hepatitis C infection)
- dronedarone (used to treat irregular heartbeat)
- ranolazine, tiapamil (used to treat chest pain)
- telmisartan, verapamil, felodipine (used to treat high blood pressure)
- lapatinib (used to treat breast cancer)
- ticagrelor (used to prevent heart attack or stroke)
- vandetanib (used to treat certain cancers of the thyroid gland)
- P-glycoprotein inhibitors
- venetoclax (is used to treat patients with chronic lymphocytic leukaemia)
- vemurafenib (used to treat adult patients with a type of cancer called melanoma)
- Proton pump inhibitors (PPIs) (used to relieve symptoms of acid reflux, or gastroesophageal reflux disease (GERD)).

The following medicines may increase or have no effect on the levels of digoxin in the blood:

- nifedipine, diltiazem, angiotensin receptor blockers (ARBs) and ACE inhibitors (used to treat high blood pressure and congestive heart failure)
- non-steroidal anti-inflammatory drugs (NSAIDs) and cyclooxygenase-2 enzyme (COX-2) inhibitors (used to treat pain and inflammation).

If you have heart failure and are taking sennosides (increase the amount of stools you produce to help you have bowel movements) along with Digoxin tablets you may have a moderately increased risk of digoxin toxicity.

The following medicines reduce the level of digoxin in the blood:

- antacids (used to treat gastric acidity)
- some bulk-forming laxatives (increase the amount of stools you produce to help you have bowel movements)
- kaolin-pectin (used to treat diarrhoea)
- acarbose (used to treat some types of diabetes)
- certain antibiotics: neomycin, penicillamine, rifampicin
- some cytostatic drugs (used as chemotherapy for cancer treatment)
- metoclopramide (a product for treating nausea and vomiting)
- sulfasalazine (a product to counteract inflammatory diseases of the intestine)
- adrenaline (used to treat severe allergic reactions)
- salbutamol (a product used to treat asthma)
- colestyramine (lowers blood cholesterol)
- phenytoin (used to treat epilepsy)
- St. John's wort (*Hypericum perforatum*) (used to treat depression)
- bupropion (used to treat depression)
- P-glycoprotein inducers
- supplemental enteral nutrition (being fed by a feeding tube).

If you are taking Digoxin tablets along with the following medicines, you may have an increased risk of irregular heart rhythm:

- intravenous calcium
- beta-blockers
- sympathomimetics (used to treat heart attack and low blood pressure).

If you are taking Digoxin tablets and saxamethonium (used to help muscle relaxation and treat short-term paralysis), you may have an increased risk of high potassium levels in the blood.

Digoxin tablets with food and drink

This medicine may be taken on an empty stomach or with most meals, however, you should avoid taking Digoxin tablets with foods high in fibre, also know as dietary fibre, because the level of digoxin absorbed by the body can be reduced.

Pregnancy and breastfeeding

Pregnancy
Your doctor will prescribe this medicine with caution during pregnancy. You may require a higher dose of this medicine if you are pregnant. This medicine could be given to the mother to treat abnormally high heart rate and congestive heart failure in the unborn child. Side effects of Digoxin tablets treatment affecting the mother may also affect the unborn child.

Breastfeeding

This medicine is excreted in breast milk, but in very small amounts. Therefore, this medicine can be used by women who are breast-feeding.

If you are pregnant or breast-feeding, think you may be

pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Since dizziness and blurred or yellow vision have been reported, you should exercise caution before driving a vehicle, using machinery or participating in dangerous activities.

Digoxin tablets contain lactose

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

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. 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 you 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.

The main symptoms of digoxin toxicity are heart rhythm disturbances and gastrointestinal symptoms which may happen before heart rhythm disturbances. Gastrointestinal symptoms include loss of appetite, nausea and vomiting. Other symptoms of digoxin toxicity include dizziness, fatigue, a general feeling of being unwell and various neurological disturbances including visual disturbances (more yellow-green than usual). The neurological and visual symptoms may persist even after other signs of toxicity have been resolved. In chronic toxicity, non-heart related symptoms, such as weakness and a general feeling of being unwell, may be the main symptoms.

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, this medicine 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:

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

- 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)

- allergic reactions of the skin may occur (rash, urticaria)
- abnormal heartbeat
- nausea, vomiting, diarrhoea
- central nervous system disturbances such as dizziness
- visual disturbances (blurred or yellow vision)

Uncommon (may affect up to 1 in 100 people)

- depression

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.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Digoxin tablets

Keep this medicine 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 carton. The expiry date refers to the last day of that month.

Do not throw any medicines away via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Digoxin tablets contain

- The active substance (the ingredient that makes the tablets work) is digoxin. Each tablet contains either 62.5microgram 125microgram or 250microgram of the active ingredient.
- The other ingredients are lactose, magnesium stearate, maize starch and pregelatinised maize starch (all 3 strengths), stearic acid (250microgram only), indigo carmine (E132) (62.5microgram only).

What Digoxin tablets look like and contents of the pack Digoxin tablets 62.5 micrograms are blue, circular, flat bevelled edge, uncoated tablets impressed "C" on one face and the identifying letters "DD" on the reverse. Digoxin tablets 125 micrograms are white, circular, flat bevelled-edge, uncoated tablets impressed "C" on one face and the identifying letters "DF" on the reverse. Digoxin tablets 250 micrograms are white, circular, biconvex, uncoated tablets impressed "C" on one face and the identifying letters "DG" on the reverse.

Digoxin tablets are available in pack size of 28

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