Package Leaflet: Information for the User

Digoxin 125 micrograms tablets
digoxin

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Digoxin tablets is and what it is used for
2. What you need to know before you use Digoxin tablets
3. How to use Digoxin tablets
4. Possible side effects
5. How to store Digoxin tablets
6. Contents of the pack and other information

1. What Digoxin tablets is and what it is used for

Digoxin tablets contains the active substance digoxin, which belongs to a group of medicines called cardiac glycosides. It is used to treat arrhythmias and heart failure. An arrhythmia is an irregularity in the heart-beat, which causes the heart to skip a beat, beat irregularly or beat at the wrong speed. This medicine works by correcting irregular heartbeats to a normal rhythm and strengthens the force of the heart-beat, which is why it is useful in heart failure.

2. What you need to know before you use Digoxin tablets

Do not use 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, pharmacist or nurse before using this medicine:
- 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.
- If you 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.
- If you 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.

- If you 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 heart-beat. Sometimes this will cause tiredness, weakness and dizziness and when your heartbeat is very slow you may faint.
- If you 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.
- If you 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.
- If you have Beri-beri disease (caused by a vitamin B1 deficiency).
- If you have constrictive pericarditis (inflammation of the sac which contains the heart).
- If you 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. Do not stop taking digoxin without talking to your doctor.
- If you have a heart test called an ECG (electrocardiogram), tell the person doing the test that you are taking digoxin as it can affect the meaning of the results.
- If you have severe respiratory (lung) disease (as you may have an increased sensitivity to digoxin).
- If you 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.
- If you have thyroid disease (such as an under-active or over-active thyroid) as you might require changes in the dose of this medicine.
- If you have malabsorption syndrome (you cannot absorb minerals from your food properly) or if you have ever had gastrointestinal reconstruction surgery.
- If you will receive electric shock treatment to correct an abnormal heart-beat.

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 (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),
- medicines used for fungal infections (isavuconazole, itraconazole, posaconazole),
- 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),
- cyclosporine (an immunosuppressant often used to prevent transplant rejection),
- epoprostenol (used to treat pulmonary arterial hypertension),
- tolvaptan (used to treat low blood sodium levels),
- 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),
- taleprevir (used to treat hepatitis C infection),
- dronedarone (used to treat irregular heart-beat),
- ranolazine (used to treat chest pain),
- simeprevir (used in combination with other medications to treat hepatitis C),
- telmisartan (used to treat high blood pressure),
- medicines used for cancer (lapatinib, vandetanib, Vemurafenib, osimertinib),
- ticagrelor (used to prevent heart attack or stroke),
- verapamil (used to treat high blood pressure),
- felodipine (used to treat high blood pressure),
- tiapamil (used to treat chest pain),
- velpatasvir (used in combination with other medications to treat hepatitis C),
- P-glycoprotein inhibitors.
- Venetoclax (is used to treat patients with chronic lymphocytic leukaemia)
- Proton pump inhibitors (PPIs) (used to relieve symptoms of acid reflux, or gastroesophageal reflux disease (GERD)

The following medicines may <u>increase or have no effect on the levels of digoxin</u> 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 you may have a moderately increased risk of digoxin toxicity.

The following medicines <u>reduce the level of digoxin</u> 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 along with the following medicines you may have an <u>increased risk of irregular heart rhythm</u>:
- intravenous calcium

- beta-blockers
- sympathomimetics (used to treat heart attack and low blood pressure),

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

Tell your doctor if you take a medicine containing enzalutamide (for the treatment of prostate cancer). It may interfere with your digoxin tests.

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 that are high in fibre, also known as 'dietary fibre', because the level of digoxin absorbed by the body can be reduced.

Pregnancy, breastfeeding and fertility

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 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.

Fertility
There is no information available on the effect of digoxin on fertility.

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
Digoxin tablets contain lactose (a sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Digoxin tablets

This medicine is available as a tablet taken orally.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will have decided how much of this medicine is right for you:
- It depends on what heart problem you have and how serious it is.
- It also depends on your age, weight and how well your kidneys work.
- While you are taking this medicine, your doctor will take regular blood tests. This is to determine how you are responding to treatment.

- Your doctor will adjust your dose based on your blood test results and on how you are responding to treatment. This is why you must strictly adhere to the treatment course prescribed your doctor.
- If you have taken another cardiac glycoside in the past 2 weeks, your doctor may prescribe a lower dose.
- If you feel that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

Taking this medicine
You usually take this medicine in two stages:

- Stage 1 - loading dose

The loading dose gets your digoxin levels up to the correct level quickly. You will either:
- take one large single dose and then begin your maintenance dose or
- take a smaller dose each day for a week and then begin your maintenance dose

- Stage 2 - maintenance dose

After your loading dose you will take a much smaller dose every day, until your doctor tells you to stop.

Oral Administration

Adults and children over 10 years
- loading dose
  - Usually between 750 and 1500 micrograms as a single dose
  - For some patients, this may be given in divided doses 6 hours apart
  - Alternatively, between 250 and 750 micrograms may be given each day for a week
- maintenance dose
  - Your doctor will decide this, depending on your response to digoxin
  - It is usually between 125 and 250 micrograms daily

Children under 10 years
- loading dose
  - This is worked out using your child's weight
  - Usually between 25 and 45 micrograms per kg of body weight
  - This should be given in divided doses between 4 and 8 hours apart
- maintenance dose
  - The doctor will decide this, depending on your child's response to digoxin
  - It is usually a 1/5 (fifth) or a 1/4 (quarter) of the loading dose, to be taken daily

Elderly
Elderly people may be given a lower dose than the usual adult dose. This is because older people may have reduced kidney function. Your doctor will check the levels of digoxin in your blood and may change your dose if necessary.

If you use more Digoxin tablets than you should
If you have taken too much of the Digoxin tablets or a child has taken the medicine by accident, contact your doctor, hospital or poison centre to evaluate the risks and get more information.

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 use Digoxin tablets

Do not take a double dose to make up for the forgotten dose.

If you stop using Digoxin tablets
Your doctor will tell you how long you should take digoxin. Do not stop your treatment early without consulting your doctor.

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

4. Possible side effects

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

If you get any of the following, talk to your specialist doctor straight away or seek urgent medical advice:
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 heart-beat
- 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.
Website: 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 medicine.

5. How to store Digoxin tablets

- Keep out of the reach and sight of children.
- Do not use digoxin after the expiry date on carton, bottle label, or blister pack (Exp.). The expiry date refers to the last day of that month.
- Store below 25°C.

- 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 contains
- The active ingredient is digoxin, each tablet contains 125 micrograms.
- The other ingredients are lactose monohydrate, maize starch, modified maize starch, rice starch and magnesium stearate.

What Digoxin tablets looks like and contents of the pack
Within the carton is an amber glass bottle that contains 500 white tablets, or a blister pack of 30 white tablets. A white, round, flat tablet debossed “DO12" on the one side and plain on the other side.

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Leaflet date: August 2025