

 PACKAGE LEAFLET:
Information for the patient

DIGOKSINE

Tablets - 0.25 mg
(Digoxin)

Read 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, ask your doctor or pharmacist.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Digoxine is and what it is used for
2. Before you take Digoxine
3. How to take Digoxine
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6. Further information

1. WHAT DIGOKSINE IS AND WHAT IT IS USED FOR

Digoxin is a digitalic cardiac glycoside used in the treatment of supraventricular arrhythmia, and especially in atrial fibrillation and heart failure. Its main action is to increase the contractility of the heart muscle and also slowing down the heart conduction, especially through atrioventricular node. Digoxin exerts a direct action on smooth muscles of blood vessels and a non-direct action starting from autonomic nervous system and especially by increased vagal activity.

Alterations of autonomic activity reflexes that depend from effects on circulatory system are also observed. Especially these effects result in positive inotropic effect, negative chronotropic effect and in slowing down the activity of atrioventricular node. In conclusion, the beneficial effects of digoxin are a result of direct actions on heart muscle, as well as of the indirect action on the cardiovascular system due to the effects on the autonomic nervous system.

Digoxine is used in:

1. supraventricular arrhythmias
2. heart failure.

2. BEFORE YOU TAKE DIGOKSINE

Do not take Digoxine if you:

- are hypersensitive to digoxin, to any other digitalic glycoside or to any of the other excipients of the tablet;
- suffer from ventricular tachycardia or ventricular fibrillation;
- suffer from supraventricular arrhythmia caused by Wolff - Parkinson - White syndrome;
- suffer from arrhythmia due to cardiac glycoside intoxication;
- have a complete or second-degree heart block, especially if the patient has had at any time a Stokes - Adams attack;
- have hypertrophic obstructive cardiomyopathy.

Calcium salt injections are contraindicated during digoxin treatment because they can cause severe arrhythmia.

If you think you suffered any of the above-mentioned situations, do not take the tablets, inform your doctor and follow up the given medical advice. If you visit any other doctor or dentist, please inform them you are under digoxin treatment.

Take special care with Digoxine

Inform your doctor if you:

- have impaired liver or renal function;
- have just had a myocardial infarction;
- have hypothyroidism;
- are taking corticosteroids, because they should not be used during Digoxine treatment because they can cause hypokalaemia.

During treatment, serum electrolytes and renal function should be examined.

Taking other medicines

Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Inform your doctor if you are taking any of the following:

- alprazolam, amiodarone, anticholinergics, benzodiazepines

cyclosporine, diltiazem, diphenoxylate, erythromycin, esmolol, felodipine, flecainide, hydroxychloroquine, ibuprofen, indomethacin, itraconazole, captopril, nifedipine, omeprazole, propafenone, propantheline, quinidine, quinine, tetracycline, tolbutamide and verapamil; these drugs may increase digoxin levels in plasma, increasing its therapeutic and toxic effect;

- aminoglutethimide, aminoglycosides (oral use), cholestyramine, cholestipol, metoprolol, neomycin, penicillin, rifampin, sucralfate, and sulfasalazine because they can reduce the gastrointestinal absorption of digoxin and digitalic glycosides, apparently reducing serum levels and therapeutic effects;
- other drugs that might interact with cardiac glycosides, as: albuterol, amphotericin B, beta-blockers, loop diuretics, disopyramide, calcium salts, non-depolarizing myorelaxants, potassium-sparing diuretics, succinylcholine, sympathomimetics, thiazide diuretics, thioamine and thyroid hormones.

These drugs may be affected by digoxin, or may affect the way it acts. You may need to use different quantities of this drug or take other drugs. Your doctor or pharmacist will advise you.

Taking Digoxine with food and drinks

No data available.

Pregnancy

Talk to your doctor or pharmacist if you are pregnant, or if you are planning to become pregnant. The use of Digoxine during pregnancy is not contraindicated. However, it is recommended to be used after considering the therapeutic benefits for the mother with potential risks for the fetus.

Breast-feeding

Inform your doctor or pharmacist if you breast-feed your baby. Digoxin is not contraindicated during breast-feeding. Your doctor or pharmacist will inform you about the risks and benefits of taking it if you are breast-feeding or you are planning to do it.

Driving and using machines

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

Important information about some of the excipients of Digoxine

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

3. HOW TO TAKE DIGOKSINE

Please follow the doctor's advice on the administration route and dosage of Digoxine.

Tablets are taken with food and a glass of water. We recommend to take them at the same time each day.

The dosage is established personally for each patient considering age, body weight and renal function. It should be noted that the recommended doses are just for the initial treatment with digitalics.

Dosage for patients with chronic heart failure in absence of supraventricular arrhythmia

In this case a loading dose is not required. Usually daily dosage is 0.125 mg up to 0.25 mg for patients with normal renal function. For the elderly, daily dosage is 0.0625 mg.

Dosage for the management of atrial fibrillation or fast heart beat in adults and children over 10 years

Rapid loading dose:

When necessary, and a fast digitalisation is required, the

recommended dosage is:

0.75 up to 1.5 mg as a single dose.

In those cases when the required digitalisation is not urgent or the possibility for toxicity is higher, e.g. in the elderly, the oral loading dose should be given in divided doses, with a difference of 6 hours from each other, in order to have a clinic response before the next dose is given.

Slow loading dose:

Digitalisation might be achieved slower through doses 0.25 up to 0.75 mg, dose which is given once daily for one week, followed by a specific maintenance dose. The clinical response is observed starting from the first week of treatment.

Attention! The decision whether choosing a rapid loading dose or the slow one depends on the patient clinical status and if the need for the treatment is urgent or not.

Maintenance dose:

Usually, the maintenance dose of digoxin is 0.125 mg up to 0.25 mg daily, but it might vary also from 0.0625 to 0.5 mg daily. In the elderly, therapy must be initiated slowly and in lower doses.

Use in children

Children doses are complex and based on body weight, stages of development of the child and on the response of the child to digitalic therapy.

Use in the elderly

For the use of digoxin in the elderly, their renal function and body weakness must be considered because these are factors that affect digoxin pharmacokinetics.

However, your doctor might advise you to receive another dose

depending on your situation and your reaction to the drug.

Talk to your doctor for any advise if you are not sure how to take this medicine.

If you take more Digoxine

If you take more Digoxine than you should, or if the children take it by mistake, please contact your doctor or hospital straight away for receiving any advice on the risks or the actions to be taken.

If you forget to take Digoxine

If you forget to take a dose, take the next dose at its usual time.

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

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

4. POSSIBLE SIDE EFFECTS

All medicines might cause side effects. Sometimes they are serious, mostly they are not. Do not get worried from this list of possible side effects. No one of them might appear to you.

Inform your doctor if any of the below-listed side effects disturbs you:

- cardiovascular side effects: arrhythmia (supraventricular arrhythmias are most common in infants and children), including premature ventricular tachycardia;
- central nervous system effects: headache, weakness, apathy, sleepiness, mental depression, confusion, disorientation. Anorexia, nausea, vomiting, diarrhea and visual disturbances have also been observed.

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE DIGOKSINE

Keep out of the sight and reach of children.

Do not use Digoxine after the expiration date stated on the packaging.

Store below 25°C.

6. FURTHER INFORMATION

What Digoxine contains?

The active substance is digoxin.

Each tablet contains 0.25 mg digoxin.

The other ingredients are: lactose monohydrate, maize starch, microcrystalline cellulose, povidone, magnesium stearate.

Content of the pack

Box with 30 tablets.

Explanatory of the illustration icons on the packaging:

 Ask your doctor or pharmacist.

 Content.  Warning.  Tablet shape.

Marketing Authorisation Holder and Manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
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Tirana - Albania

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