

Digoxin–Kern Pharma 0.25 mg Tablets

Active ingredient: Each tablet contains: **Digoxin 0.25 mg**
For the inactive ingredients in the preparation - see section 6 "Further Information".

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others; it may harm them even if it seems to you that their medical condition is similar.

If this is the first time you are taking Digoxin–Kern Pharma, the doctor may want to monitor the levels of the medicine in your blood. Consult the doctor.

If you have previously taken Digoxin produced by a different company, there may be changes in the levels of medicine detected in the blood compared to the medicine you have taken until now. Therefore, the doctor may want to monitor the blood levels of the medicine and to closely follow the effect of the medicine. Consult the doctor.

1. WHAT IS THE MEDICINE INTENDED FOR?

Regulation of heart rate disorders.
For treatment of heart failure.

Therapeutic group: Cardiac glycosides.

Digoxin slows the heart rate while increasing the force of the contraction of the heart, thereby leading to more effective cardiac activity.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient, to digitalis/other glycosides or to any of the ingredients of the medicine.
- you have been told that you have one of the following heart problems:
 - a partial or a second-degree heart block.
 - certain types of supraventricular arrhythmias.
 - ventricular tachycardia or ventricular fibrillation.
 - hypertrophic obstructive cardiomyopathy.

Special warnings regarding use of the medicine

- **Use this preparation only under a doctor's supervision and monitoring.**
- Discontinuing digoxin has been found to cause clinical deterioration among patients receiving diuretics in combination with ACE inhibitors, or diuretics only.
- Caution should be exercised when giving **Digoxin–Kern Pharma** to patients with a thyroid disorder. The starting dosage and the maintenance dosage of **Digoxin–Kern Pharma** must be reduced when thyroid activity is low. For hyperthyroidism (overactive thyroid), there is relative resistance to digoxin, and the dosage must be increased. When treating thyrotoxicosis (a toxic condition resulting from hyperthyroidism), the dosage should be reduced only to the point at which the disease can be controlled.

Do not use this medicine without consulting a doctor before commencing treatment if:

- you recently had a heart attack.
- you are suffering from an electrolyte imbalance in the body (high calcium levels or low potassium or magnesium levels).
- you are suffering from a heart problem caused by vitamin B deficiency (Beri-Beri disease).
- you are suffering, or have suffered in the past, from problems of the digestive system.
- you are suffering, or have suffered in the past, from impaired function of: the lungs (respiratory disease, low oxygen levels in the blood), the kidney, thyroid.
- If you have a pacemaker.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

- Medicines to treat the digestive system, including: antacids, antiemetics and antidiarrheals, laxatives.
- Medicines to treat the heart, including: to treat hypertension or heart rate disorders.
- Verapamil, felodipine (to treat hypertension) – increase serum digoxin levels.
- Nifedipine, and diltiazem (to treat hypertension) – may increase or may not affect serum digoxin levels.
- Medicines to treat respiratory problems (e.g., asthma, such as: salbutamol).
- Medicines to treat cancer.
- Medicines to treat epilepsy.
- Medicines to treat anxiety or depression.
- Antibiotics to treat bacterial infections.
- Medicines to treat fungal infections.
- Medicines to lower cholesterol.
- Medicines to prevent organ transplant rejection.
- Medicines to treat immune system problems.
- Medicines to prevent blood clots during kidney dialysis.
- Diuretics.
- Steroids.
- Anesthetics.
- Muscle relaxants.
- Medicines to treat diabetes (e.g., acarbose).
- Medicine to treat the thyroid.
- Non-steroidal anti-inflammatory drugs - NSAIDs.
- The herbal medicine St. John's Wort (to treat depression).
- Medicines which contain vitamin D, calcium and calcium supplements.
- If you took other cardiac glycosides in the two weeks preceding commencement of treatment with this medicine, your doctor may want to reduce the dosage.

Use of the medicine and food

This medicine can be taken with most types of food, but it is preferable to avoid taking the medicine with fiber-rich foods (e.g., whole wheat flour, cereals, grains, fruits and vegetables), as they may reduce absorption of the medicine.

Pregnancy and breastfeeding

If you are pregnant, may become pregnant or are breastfeeding - consult the doctor before using this medicine.

Digoxin is not contraindicated during pregnancy. Nevertheless, as with any other medicine, the doctor will consider whether the expected clinical effect on the mother outweighs the possible risk to the unborn baby and, if necessary, will adjust the dosage, as effects have been observed in unborn babies when serum digoxin levels were toxic.

Breastfeeding – digoxin passes into breast milk, in low quantities; consult the doctor.

Driving and using machinery

You may experience dizziness, tiredness, headache or suffer from blurred vision due to taking digoxin. If these effects occur, do not drive or use dangerous machinery.

Important information regarding some of the ingredients of the medicine

The preparation contains lactose. Inform the doctor if you suffer from intolerance to certain sugars.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only, depending on individual variables (age, weight and kidney function) and the heart problem you are suffering from.

The doctor will consider recommending a change in the dosage (loading and maintenance) in older patients or in patients with low kidney function.

Treatment will generally have two phases:

"Loading dose" – the objective of this dose is to rapidly increase the levels of the medicine in the blood. To achieve this, one high dose can be taken and immediately afterwards, switch to a maintenance dose or take a relatively low dosage for one week and then switch to the maintenance dose.

"Maintenance dose" – after taking the loading dose, a much lower dosage is taken, as per the doctor's judgment.

Dosage – according to the doctor's instructions only!

Do not exceed the recommended dose.

Swallow the medicine with water. The tablet can be crushed/halved.

Tests and follow-up

During the course of treatment, the doctor may want to perform blood and urine tests to assess how the medicine affects you and will accordingly decide whether there is a need to change the dosage.

If you took a higher dosage than required, or if a child accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of this medicine with you. This condition may be life-threatening. You may develop side effects as detailed in section 4, .

If you forgot to take this medicine at the schedule time, take the dose when you remember, but if the time you remembered is close to the next dosing time, consult a doctor. Do not take a double dose.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor or pharmacist, as the heart condition may worsen.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Digoxin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them. In general, digoxin side effects will mostly occur as a result of taking a higher dosage than required; therefore, the doctor may want to change the dosage.

Refer to a doctor immediately if the following effects develop:

- Signs which may indicate a heart problem arising from a new heart rate disorder (due to the medicine), such as: strong palpitations, chest pain, shortness of breath or sweating.
- Hypersensitivity to the medicine (extremely rare). Symptoms include rash, swelling of the face, lips, tongue, difficulty breathing or swallowing.

Additional side effects that **must be reported to the doctor:**

Common:

- Irregular or slow heart rate
- Vomiting and nausea, diarrhea
- Skin rash, which may cause itching
- Dizziness or sleepiness
- Impaired vision, such as blurred vision or seeing in yellow-green colors

Uncommon:

- Depression

Very rare:

- Tendency to bruise or bleed more than usual
- Abdominal pain resulting from damage to the intestine and/or lack of blood flow to the stomach
- Mental disturbances (confusion, indifference, inability to judge clearly)
- Tiredness or weakness, general feeling of being unwell
- Breast enlargement (in men)
- Loss of appetite
- Headache
- Severe heart rate disturbances

If any of the side effects worsen, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

Special effects in children

Children are particularly sensitive to developing side effects following use of digoxin, such as: loss of appetite, nausea, vomiting or diarrhea. In addition, cases of irregular or rapid heart rate have been reported.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 30°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains: Lactose monohydrate, maize starch, rice starch, hydrolyzed maize starch, magnesium stearate.

Each tablet contains 96 mg lactose monohydrate.

What does the medicine look like and what are the contents of the pack?

A round, white tablet with a scoreline.

License holder: Trima Trading (1961) Ltd., Maabarot 4023000, Israel.

Manufacturer: Kern Pharma S.L., Poligono Industrial Colón II, Venus, 72, 08228 Terrassa (Barcelona), Spain.

This leaflet was checked and approved by the Ministry of Health in January 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 151.20.33918.00