PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Droncor

Film-coated tablets

Active ingredient

Each film-coated tablet contains dronedarone
400 mg (as hydrochloride)
Inactive and allergenic ingredients in the medicine see in section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine.
Keep this leaflet; you may need to read it again.
This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor or pharmacist.
This medicine was prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is used to treat atrial fibrillation after return to normal heart rhythm (sinus rhythm).

Therapeutic group: anti-arrhythmic preparation to regulate heart rhythm.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6 "Further Information").
- You are suffering from nerve conductivity disturbances in the heart, manifested by slow heart rate or feeling dizzy. If you have a pacemaker, you can use **Droncor**.
- You are suffering from a very slow heart rate (less than 50 beats per minute).
- ECG shows a heart problem called "prolonged QT interval" (a segment of more than 500 milliseconds).
- You have chronic atrial fibrillation (fibrillation that persists continuously for at least 6 months) and a decision was made not to change your sinus rhythm back by cardioversion.
- You are suffering from instability (drops) in blood pressure which may lead to inadequate arterial blood flow to the organs of the body.
- You are suffering or have suffered in the past from heart failure that could manifest by edema in the legs, breathing difficulties when lying down or sleeping, or shortness of breath when moving.
- The volume of blood leaving the heart each time it contracts is too low (left ventricular dysfunction).
- You took amiodarone in the past and developed lung or liver side effects.

- You take medicines to treat infection (including fungal infection or AIDS), allergies, heart rate problems, depression, medicines after a transplant (see in section 2 “Drug interactions”).
- You are suffering from severe liver function problems.
- You are suffering from severe kidney function problems.
- You are taking dabigatran (to prevent formation of blood clots) (see in section 2 “Drug interactions”).

If any of these conditions apply to you, do not use **Droncor**.

Special warnings regarding use of the medicine

Before using Droncor, tell the doctor if:

- You are suffering from a problem that causes low levels of potassium or magnesium in the blood. Treat this problem before you start using **Droncor**.
- You are over 75 years of age.
- You have a condition in which the blood vessel that supplies blood to the heart muscle becomes hardened and narrowed (coronary artery disease).

During treatment with the medicine, tell the doctor if:

- Your atrial fibrillation has become chronic during the course of treatment with **Droncor** – stop treatment with **Droncor**.
- You have swollen feet or legs, breathing difficulties when lying down or sleeping, shortness of breath during activity, or weight increase (these are signs and symptoms of heart failure).
- Tell the doctor immediately if you develop any of the following signs or symptoms of a liver problem: stomach (abdominal) area pain or discomfort, loss of appetite, nausea, vomiting, yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, fatigue (especially in association with other symptoms listed here), itching.
- You are suffering from breathlessness or a dry cough. Tell the doctor so he/she will check your lungs.

If the above-mentioned applies to you (or in case of doubt), please consult with the doctor or pharmacist before taking **Droncor**.

Tests and follow-up

While using **Droncor**, the doctor may perform tests to check your medical condition and the effect of the medicine on you.

- The doctor may check your heart’s electrical activity using an ECG (electrocardiogram) machine.
- The doctor will send you for a liver function blood test before you start and during treatment with **Droncor**.
- If you are taking medicines against blood clot formation, such as warfarin, the doctor will send you for a blood test called INR to check if the medicine is working well.
- The doctor may also do other blood tests. The result of one of the tests to check kidney function (blood creatinine levels) may be affected by **Droncor**. The doctor will take this into account when checking blood test results and will use another reference value for the “normal” value.
- The doctor may perform a lung test.

In some cases, **Droncor** treatment may need to be stopped.

Please inform the person checking your blood test results that you are taking **Droncor**.

Children and adolescents

Droncor is not recommended in children and adolescents below 18 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

Your doctor may recommend that you use a medicine against blood clot formation according to your condition.

Droncor and other medicines may affect each other and cause serious side effects. The doctor may change the dosage of other medicines you are taking.

Do not take the following medicines together with **Droncor**:

Other medicines used to treat heart rate disturbances (arrhythmia), such as: flecainide, propafenone, quinidine, disopyramide, dofetilide, sotalol, amiodarone.

Medicines for treatment of fungal infections, such as: ketoconazole, voriconazole, itraconazole or posaconazole.

Medicines from the tricyclic antidepressant group (to treat depression).

Medicines from the phenothiazine group (for sedation).

Bepridil for chest pain caused by heart disease.

Telithromycin, erythromycin, or clarithromycin (antibiotics to treat infections).

Terfenadine – to treat allergy.

Nefazodone – to treat depression.

Cisapride – to treat reflux of food and acid from the stomach to the mouth.

Ritonavir – to treat AIDS infections.

Dabigatran – to prevent blood clot formation.

Inform the doctor or pharmacist if you are taking any of the following medicines:

Medicines to treat high blood pressure, chest pain caused by heart disease, or other heart problems, such as: verapamil, diltiazem, nifedipine, metoprolol, propranolol or digoxin.

Medicines for reducing blood cholesterol, such as: simvastatin, lovastatin, atorvastatin or rosuvastatin.

Anticoagulants, such as warfarin, rivaroxaban, edoxaban and apixaban.

Medicines to treat epilepsy: phenobarbital, carbamazepine or phenytoin.

Medicines to prevent transplant rejection: sirolimus, tacrolimus, everolimus, cyclosporine.

A herbal medicine to prevent depression – St. John's Wort (*Hypericum*).

Rifampicin – for tuberculosis.

Use of the medicine and food

Take one tablet in the morning, with food, and one tablet in the evening, with food.

Do not drink grapefruit juice while taking **Droncor**, as it can increase the level of the active ingredient, dronedarone, in the blood and thereby increase the chance of side effects.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor.
If you are a woman of child-bearing potential, the doctor will perform a pregnancy test before you start treatment with **Droncor**.
Use of **Droncor** is not recommended if you are pregnant or think you may be pregnant.
Do not take **Droncor** if you are a woman of child-bearing age and are not using reliable contraceptive methods.
Use effective contraceptives during treatment and for 7 days after the last dose of **Droncor**.
If you get pregnant while using **Droncor**, stop taking the tablets and refer to a doctor immediately!
It is not known if **Droncor** passes into breast milk. Consult the doctor to decide whether you should take **Droncor** or breastfeed. Do not breastfeed during the course of treatment with **Droncor** and for 7 days after the last dose.
Consult the doctor or pharmacist before taking any medicine during pregnancy and when breastfeeding.

Driving and using machines

Droncor usually does not affect the ability to drive or use machines. However, the ability to drive or use machines may be affected by side effects, such as tiredness.

3. HOW TO USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.
If you need to switch from amiodarone (another medicine for treating heart rate disturbances) to **Droncor** treatment, the switch should be performed with caution.
The dosage and treatment regimen will be determined by the doctor only.
The usual dosage is generally one **Droncor** 400 mg tablet, twice a day:
One tablet in the morning, with breakfast.
One tablet in the evening, with dinner.
If you think the medicine is too strong or too weak, tell the doctor or pharmacist.

Mode of administration

Swallow the tablet whole with water, during a meal.
Do not halve the tablet. There is no information regarding crushing or chewing the tablet.
Do not exceed the recommended dose.

If you accidentally took a higher dosage

Immediately refer to your doctor or proceed to the closest emergency room. Bring the package of the medicine with you.

If you forget to take the medicine

If you forgot to take this medicine at the scheduled time, take a dose at the next usual dosing time. Never take two doses together to compensate for a forgotten dose!

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Do not stop using the medicine without consulting the doctor or pharmacist, even if there is an improvement in your health.

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

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

4. SIDE EFFECTS

As with any medicine, use of **Droncor** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The following side effects have been reported while using this medicine:

Refer to the doctor immediately if you notice any of the following serious side effects – you may need urgent medical assistance

Very common side effects (may occur in more than 1 user in 10):

- Heart failure. In clinical studies, this effect was observed at the same incidence rate in patients receiving **Droncor** and in patients receiving placebo. Signs include swelling of the feet or legs, breathing difficulties when lying down or sleeping, shortness of breath during activity, weight increase.

Common side effects (may occur in 1-10 in 100 users):

- Excessive diarrhea and vomiting, which may lead to kidney problems.
- Slow heart rate.

Uncommon side effects (may occur in 1-10 in 1,000 users):

- Inflammatory lung disease (including scarring and thickening of the lung). Signs include breathlessness or non-productive cough.

Rare side effects (may occur in 1-10 in 10,000 users):

- Liver problems, including life-threatening liver damage. The signs include: stomach (abdominal) area pain or discomfort, loss of appetite, nausea, vomiting, yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, fatigue (especially in association with other symptoms listed here), itching.
- Allergic reactions, including swelling of the face, lips, mouth, tongue and throat.

Additional side effects:

Very common side effects:

- Changes in one blood test result: creatinine blood level.
- Changes in the ECG test result (QTc Bazett prolonged).

Common side effects:

- Problems with the digestive system such as: diarrhea, nausea, vomiting and stomach pain.
- Feeling tired.
- Skin problems such as rash or itching.
- Change in the results of liver function blood test.

Uncommon side effects:
- Other skin problems such as redness of the skin or eczema (redness, itching, burning sensation or blistering).
- Increased sensitivity of the skin to sun exposure.
- Change in sense of taste.

Rare side effects:
- Loss of sense of taste.
- Inflammation of the blood vessel wall (including leukocytoclastic vasculitis).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il
Additionally, you can report to "Unipharm Ltd."

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning.
Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package/tray (blister). The expiry date refers to the last day of that month.
Storage conditions: Store below 25°C and in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Crospovidone, Maize starch, Mannitol, Poloxamer 407, Microcrystalline cellulose, Povidone, Magnesium stearate, Hydroxypropyl methylcellulose, Colloidal silicon dioxide, Opadry Y-1-700 (White).

What the medicine looks like and the contents of the package:

Droncor is packaged in trays (blisters) which are inserted into a carton package.

Droncor are film-coated, oblong, biconvex, white tablets.
Droncor is available in package sizes of 4, 7, 14, 15, 20, 28, 30 or 60 tablets.
Not all package sizes may be marketed.

This leaflet does not include all the information about the product. If you have any question or are uncertain about something, please refer to a doctor.

Registration holder and address: Unipharm Ltd., P.O.Box 16545, Tel Aviv, 6116401.
Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.
Revised in November 2024.
Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Droncor: 165 80 35478 00

אוניפארם unipharm

11C24 119698010