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

The dispensing of this medicine
is upon doctor's prescription only

Rytmonorm
150 mg, 300 mg
Film-coated tablets

Composition
Each tablet contains:
Rytmonorm 150 mg film-coated tablets
Propafenone Hydrochloride 150 mg
Rytmonorm 300 mg film-coated tablets
Propafenone Hydrochloride 300 mg

For a list of the inactive ingredients in this preparation, see section 6 – "Further information".

Read the package insert carefully and in its entirety before using the medicine. This package insert includes concise information about the medicine. If you have further questions, refer to your doctor or to a pharmacist.

This medicine was prescribed to treat your ailment. Do not pass it on to others. It may harm them, even if their medical state seems similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medication is used to regulate abnormal rhythms of the heart.

Therapeutic group:
Antiarrhythmics.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
- You are sensitive to any of its ingredients.
- You have heart failure or any heart problems other than your abnormal heart rhythm, especially if you don't wear a pacemaker.
- You have an unusually slow heartbeat or low blood pressure.
- You had a heart attack in the last three months.
- Your doctor has told you that you have myasthenia gravis (severe muscle weakness).
- Your doctor has told you that the salts (such as sodium, potassium, calcium, phosphate or others) in your blood are out of balance.
- You suffer from Brugada syndrome (a genetic heart disease which predisposes carriers to abnormal electrocardiograms and also to potentially life-threatening abnormalities of the heart rhythm when given certain drug classes, e.g., propafenone).
- You are concomitantly taking ritonavir (for AIDS).

Special warnings regarding use of this medicine
❗ Before you start to take this medicine talk to your doctor if you suffer, or have suffered in the past, from:
- Impaired function of the heart and/or vascular system
- Impaired function of the liver
- Impaired function of the kidney/urinary tract
- If you have breathing problems, such as asthma

If you are not sure if any of this list applies to you, ask your doctor or pharmacist.

❗ Additional warnings
- During treatment with this medicine, ECG tests should be performed.
- If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.
- If you are about to undergo surgery (including dental) or any operation requiring anesthesia, inform the anesthesiologist that you are taking this medicine.
- If any signs of infection occur, such as fever, sore throat or chills, report immediately to the attending doctor.
- Consult the doctor if you are consuming grapefruit juice while you are taking this medicine, since this combination can lead to an increase in the blood levels of the active ingredient propafenone.

❗ Inform your doctor or pharmacist if you are taking, or have recently taken, other medicines, including non-prescription medicines, herbal medicines or dietary supplements and vitamins; especially inform the doctor or the pharmacist if you are taking medicines from the following groups or you have just finished treatment with them:
- Anticoagulants (such as warfarin)
- Diuretics
- Digitalis (for the heart)
- Quinidine (to treat irregular heartbeat)
- Beta blockers (for the heart, such as propranolol)
- Local anesthetics (for surgery or dental use)
- Ketoconazole (antifungal)
- Erythromycin (antibiotic)
- Venlafaxine
- Fluoxetine, paroxetine (drugs for depression)
- Tricyclic antidepressants (e.g., imipramine)
- Theophylline (for asthma)
- Cyclosporine (an immunosuppressant)
- Rifampicin (for tuberculosis)
- Phenobarbital (for sedation)
- Ritonavir (for AIDS)
- Amiodarone (to treat irregular heartbeat)
- Cimetidine (for ulcer)
- Lidocaine (intravenous anesthetic)

This is not a complete list of medicines that may interfere with this medicine. Talk to your doctor or pharmacist before you start any medicines.

❗ Pregnancy and breastfeeding
Talk to your doctor if you are pregnant, planning to become pregnant, or breastfeeding.

❗ Driving and using machines
This medicine can cause blurred vision, dizziness, tiredness and low blood pressure in some people; therefore, caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery and in any other activity which requires alertness.

❗ Use in children
This medicine is not intended for use in children.

3. HOW SHOULD YOU USE THIS MEDICINE?

Always follow the doctor's instructions when using this medicine. If you are unsure, refer to your doctor or pharmacist.
The individual maintenance dose should be determined under cardiological surveillance including ECG monitoring and repeated blood pressure control (titration phase).
This medicine is to be taken at specific time intervals as determined by the attending doctor.

Do not exceed the recommended dosage.

Even if your condition improves, do not stop treatment without consulting the doctor.
Untreated hypertension can have severe consequences to your health.

Directions for use
Do not chew!
Swallow the tablets with a little water.
Take this medicine after a meal.
Rytmonorm 300 mg can be divided on the score line, however this may not be desirable due to the drug's bitter taste.
Rytmonorm 150 mg cannot be divided since there is no score line.

If you/the child accidentally took an overdose of this medicine, refer to your doctor or a hospital emergency room immediately and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by a doctor! Even if you feel good, immediate treatment is vital.

If you forget to take this medicine at the specified time, take the dose as soon as you remember, but never take a double dose on the same day.

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

4. SIDE EFFECTS

As with any drug, use of this medicine can cause side effects among some users. Do not be alarmed by the list of side effects; you may not suffer from any of them.

If the following happens to you, stop using this medicine and talk to your doctor immediately:
- Difficulty in breathing, chest pain, worsening of arrhythmia.
- Allergic reactions such as skin reddening, itching or a rash have been reported in rare cases. Allergic reactions are reversible if the treatment is stopped.
- Tell your doctor immediately if you develop a very sore throat, high fever, or chills. Tell your doctor immediately if you develop a rash or if you notice yellowing of the skin and/or eyes.

Additional side effects
Very common (affects more than 1 in 10 people)
- Dizziness
- New or worsened abnormal heartbeat
- Palpitations

Common (affects less than 1 in 10 people)
- Anxiety
- Sleep disorders
- Headache
- Taste changes
- Blurred vision
- Fast or irregular heartbeat
- Atrial flutter
- Trouble breathing
- Abdominal pain
- Vomiting, nausea
- Diarrhoea
- Constipation
- Abnormal liver function tests
- Chest pain
- Weakness
- Tiredness
- Elevation in body temperature

Uncommon (affects less than 1 in 100 people)
- Low blood platelet count
- Decreased appetite
- Nightmares
- Fainting
- Lack of muscle coordination and balance
- Paresthesia (feeling of pins and needles)
- Vertigo
- Ventricular arrhythmias
- Hypotension (low blood pressure)
- Abdominal distension
- Flatulence
- Itching
- Rash
- Redness of skin
- Impotence

Side effects occurring in an unknown number of users
- Leucopenia - very low white blood cells (fever, sore throat, chills)
- Granulocytopenia
- Agranulocytopenia
- Hypersensitivity
- Confusion
- Convulsions
- Extrapyramidal disorder (effects pertaining to the nervous system)
- Restlessness
- Ventricular fibrillation
- New or worsened heart failure (new or increased swelling in the arms or legs, trouble breathing, sudden weight increase)
- Reduction in heart rate
- Orthostatic hypotension: sudden reduction in blood pressure from sitting to standing
- Gastrointestinal disturbance
- Hepatocellular injury and cholestasis
- Hepatitis, jaundice
- Lupus-like syndrome
- Sperm count decrease

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

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not take this medicine after the expiration date (Expiry date) indicated on the package. The expiration date refers to the last day of the indicated month.
Store this medicine in a dry place, below 30°C.
Ensure that the package of the medicine is kept tightly closed at all times, in order to prevent penetration of air and humidity.
Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
Do not store different medications in the same package.

6. FURTHER INFORMATION

Aside from the active ingredient, this medicine also contains:

Rytmonorm 150 mg film-coated tablets
Microcrystalline cellulose, maize starch, carboxymethylcellulose (croscarmellose) sodium, methyl hydroxypropyl cellulose, polyethylene glycols (macrogol 400 and macrogol 6000), titanium dioxide E171, magnesium stearate.

Sodium content 0.65-0.95 mg per tablet.

Rytmonorm 300 mg film-coated tablets
Microcrystalline cellulose, maize starch, carboxymethylcellulose (croscarmellose) sodium, methyl hydroxypropyl cellulose, polyethylene glycols (macrogol 400 and macrogol 6000), titanium dioxide E171, magnesium stearate.

Sodium content 1.3-1.9 mg per tablet.

What the medicine looks like and contents of the package:
Rytmonorm 150 mg: white to off-white biconvex tablets.
Rytmonorm 300 mg: white to off-white biconvex tablets scored on both sides.

Manufacturer:
Abbott Laboratories GmbH, Hannover, Germany.

Licence holder:
Abbott Medical Laboratories Ltd., Kiryat Atidim, P.O.B. 58099, Tel-Aviv.

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

Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:
Rytmonorm 150 mg:
103.99.27103.00; 103.99.27103.12
Rytmonorm 300 mg:
104.01.27104.00; 104.01.27104.12