

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

The medicine is dispensed with
a doctor's prescription only.

RYTHMICAL 100 Capsules

RYTHMICAL 150 Capsules

Composition:

Each **Rythmical 100** capsule contains:

Disopyramide (as phosphate) 100 mg

Each **Rythmical 150** capsule contains:

Disopyramide (as phosphate) 150 mg

For the list of inactive ingredients, please see section 6: "Further Information".

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

This medicine was prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic activity: To treat cardiac arrhythmias.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- you are sensitive (allergic) to disopyramide or to any of the other ingredients contained in the medicine (see section 6: "Further Information"). The symptoms of allergy include rash, swelling of the lips, face, throat or tongue.
- you have other heart diseases, in addition to cardiac arrhythmias.
- you are taking other medicines to treat cardiac arrhythmias.
- you are taking other medicines that may cause abnormal pulse.
- you are suffering from liver or kidney problems.

Special warnings regarding use of the medicine:

❗ Before treatment with Rythmical, tell the doctor if:

- You are suffering from a low blood potassium level (hypokalemia).
- You are suffering from low blood sugar levels. This may occur if you have diabetes, are underweight, suffer from malnutrition or are elderly.
- You are suffering from glaucoma (increased intraocular pressure that may cause eye pain with blurred vision).
- You are suffering from an enlarged prostate gland.
- You are suffering from myasthenia gravis (a disease that causes muscle weakness).
- You are elderly and suffer from memory or concentration problems, or sometimes have a hard time thinking clearly.

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

Do not take Rythmical and refer to the doctor if you are taking:

- Medicines to treat cardiac arrhythmias:
 - Beta blockers such as propranolol, oxprenolol or acebutolol.
 - Verapamil (also used to treat angina pectoris and hypertension).
 - Digoxin (also used to treat heart problems).
- Medicines which when taken with **Rythmical** may increase the risk of cardiac arrhythmias:
 - Antidepressants such as amitriptyline, imipramine or maprotiline.
 - Medicines for erectile dysfunction such as sildenafil, tadalafil or vardenafil.
 - Antibiotics such as erythromycin, clarithromycin, azithromycin or sparfloxacin.
 - Antihistamines (to treat allergies) such as astemizole or terfenadine.
 - Cisapride (to treat heartburn).
 - Pentamidine (to treat pneumonia).
 - Pimozide and thioridazine (to treat schizophrenia).

Inform the doctor or pharmacist if you are taking the following medicines, since they may affect the action of Rythmical:

- Amphotericin B (to treat fungal infections).
- Tetracosactide (to treat certain hormonal problems).
- Rifampicin (to treat infections).
- Atropine (included in eye drops and cold medicines).
- Anticholinergic medicines (including certain medicines to treat irritable bowel syndrome, asthma or urinary incontinence).
- Medicines to treat emotional or mental problems or to treat nausea and vomiting (e.g., chlorpromazine or prochlorperazine).
- Diuretics, such as furosemide.
- Corticosteroids such as hydrocortisone, betamethasone or prednisolone.
- Laxatives, such as bisacodyl or senna.
- Antiepileptics such as phenobarbital, primidone or phenytoin.

Inform the doctor or pharmacist if you are taking the following medicines, since Rythmical may affect their activity:

- Antiviral medicines to treat HIV, such as zidovudine, didanosine or zalcitabine.
- Theophylline – to treat wheezing and breathing difficulties.
- Ciclosporin (to prevent rejection of transplants).
- Warfarin (a blood thinner).

❗ Pregnancy and breastfeeding: If you are pregnant, planning a pregnancy or think you are pregnant, consult the doctor before taking the medicine. If you are breastfeeding or planning to breastfeed, consult the doctor, since small quantities of this medicine pass into breast milk.

❗ Driving and use of machines: In some people, this medicine may cause impaired concentration and reaction time, blurred vision and dizziness. If you experience these effects, do not drive a vehicle or operate dangerous machinery.

❗ Important information regarding some of the medicine's ingredients: This medicine contains lactose which may cause allergy in people sensitive to lactose.

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.

The usual dosage for most patients is generally 600 mg **Rythmical** per day, administered in divided doses (150 mg every 6 hours). For patients weighing less than 50 kg, the usual dosage is 400 mg per day (100 mg every 6 hours).

Do not exceed the recommended dose.

If you feel that the effect of the medicine is too strong or too weak, do not change the dosage on your own; contact the attending doctor.

Elderly: The doctor may prescribe a lower dosage to elderly patients with liver or kidney problems.

Use in children: The medicine is not intended for children.

Blood tests: During the course of treatment with the medicine, the doctor may decide to have periodic blood tests performed to check blood sugar levels.

Swallow the medicine with water.

Do not chew, halve or open the capsule!

If you accidentally took a higher dosage or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Symptoms of overdose include dizziness, fatigue, uneven pulse, palpitations, dry mouth, difficulty passing urine, nausea or vomiting, abdominal pain, seizures (fits).

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember, but if it is almost time for the next dose, skip the forgotten dose and take the next dose at the regular time. Never take two doses together!

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose each time you take 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 **Rythmical** 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.

Refer to a doctor immediately if you experience the following side effects (you may need medical attention):

- Allergic reaction, whose signs include skin rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.

Refer to a doctor as soon as possible if you experience the following side effects:

- Faint or dizzy sensation.
- Palpitations or uneven, fast or slow pulse (symptoms that you did not experience previously or that have worsened).

Additional side effects:

Very common side effects: dry mouth, difficulty passing urine (especially in men with prostate problems), constipation.

Common side effects: nausea and vomiting; indigestion; abdominal pain; distension (flatulence); loss of appetite; diarrhea; blurred vision or double vision; dry nose, eyes or throat; urinary retention, increased urgency and frequency of urination; dizziness; general fatigue, muscle weakness (including exacerbation of myasthenia gravis, in patients with this disease); headache; malaise; aches; impotence in men; low blood pressure with or without heart failure, worsening of heart failure; heart conductivity disorders; edemas/weight gain; shortness of breath; fainting; chest pain; skin rash; itching; nervousness; low blood potassium level (hypokalemia); increased blood fat or cholesterol levels.

Uncommon/rare side effects: depression; sleep problems; anuria; numbness or tingling in the extremities, increased liver enzyme levels; cardiac arrest; increased blood urea or creatinine; anemia (reduced red blood cell counts or blood hemoglobin); low blood sugar level (hypoglycemia), whose signs are sweating, paleness, headache, feeling faint or dizzy; jaundice (yellowing of the skin or eyes); fever; breathing difficulties; reduced blood platelet count (thrombocytopenia); reduced white blood cell counts (agranulocytosis), which may lead to a tendency to get infections; breast enlargement in men; symptoms of lupus; psychotic symptoms.

Side effects of unknown frequency: mood swings, changes in mental state; memory disturbances; concentration disorders.

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

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 unless explicitly instructed to do so by 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 below 25°C and in a place protected from light.

6. FURTHER INFORMATION

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

Lactose, Maize starch, Povidone, Magnesium stearate, Gelatine capsule.

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

Rythmical is marketed in packs of 30 capsules packaged in trays (blisters). **Rythmical 100** are pink-white capsules, and **Rythmical 150** are red-white capsules.

License holder: Unipharm Ltd., P.O.B. 21429 Tel Aviv 6121301.

Manufacturer and address: Trima Ltd., Kibbutz Maabarot.

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

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

Rythmical 100: 040 94 22824 00

Rythmical 150: 041 13 22825 00