

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

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

Ripalid 0.5 mg Ripalid 1 mg Ripalid 2 mg Tablets

Each tablet of Ripalid 0.5 mg contains Repaglinide 0.5 mg
Each tablet of Ripalid 1 mg contains Repaglinide 1 mg
Each tablet of Ripalid 2 mg contains Repaglinide 2 mg
Inactive ingredients: see section 6 in the leaflet.

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. Keep this leaflet; you may want to read it again.

This medicine has been 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. If any of the side effects worsen or when you suffer from a side effect not mentioned in this leaflet, consult a doctor or pharmacist. The medicine is intended for treatment of adults above the age of 18 and under the age of 75.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ripalid is intended for treatment of Type 2 diabetes in adults, as an add-on to diet and exercise: treatment is usually started when diet, weight reduction or exercise alone have not been able to control or lower your blood sugar level.

Ripalid treatment can also be combined with metformin – another medicine for diabetes.

Ripalid is an oral Type 2 antidiabetic medicine, containing repaglinide which helps the pancreas produce more insulin and thereby lowers the blood sugar (glucose) level.

Type 2 diabetes is a disease in which the pancreas does not secrete enough insulin to regulate the blood sugar level or when the body does not respond normally to the insulin it produces.

Ripalid has shown efficacy in lowering the blood sugar level, which helps prevent complications from your diabetes.

Therapeutic group: medicines for the treatment of diabetes from the meglitinide group.

2. BEFORE USING THE MEDICINE

❗ Do not use Ripalid if:

- you are **sensitive** (allergic) to the active ingredient repaglinide or to any of the additional ingredients contained in the medicine (see section 6 in this leaflet).
- your diabetes is **type 1 diabetes** (insulin-dependent diabetes).
- you have raised acid levels in the blood (diabetic ketoacidosis).
- you have a **severe liver disease**.
- you are being treated with **gemfibrozil** (a medicine to lower the level of fats in the blood).

Special warnings regarding use of the medicine

❗ Before treatment with Ripalid, tell the doctor:

- If you have liver function problems. Ripalid is not recommended in patients with moderate liver disease. Ripalid should not be used in the case of severe liver disease.
- If you have **kidney function problems**. Ripalid should be taken with caution.
- If you are about to have **major surgery** or you have recently suffered from a **severe illness or infection**. In such cases diabetic control may be lost.
- If you are **under the age of 18 or over the age of 75**, treatment with Ripalid is not recommended. There have been no studies conducted regarding treatment with the medicine in these age groups.

Tell the doctor if any of the conditions apply to you. Ripalid may not be suitable for you. The doctor will instruct you what to do.

❗ Children and adolescents – The medicine is not intended for children and adolescents under the age of 18.

❗ If you experience a 'hypo' (low blood sugar level):

You may experience 'hypo' (short for hypoglycemia: low blood sugar level) which may happen in the following cases:

- If you take too much Ripalid
- If you exercise more than usual
- If you take additional medicines or if you suffer from liver or kidney problems (see sub-sections later on regarding use of other medicines).

Warning signs of hypoglycemia, which may come on suddenly, include: cold sweat, cold pale skin, headaches, rapid heartbeat, nausea, a sensation of extreme hunger, temporary changes in vision, dizziness, unusual tiredness and weakness, nervousness or tremor, anxiety, confusion, concentration difficulties.

If your blood sugar level is low or if you feel a hypoglycemic event coming on, you should take a sugar tablet or any other high-sugar food or drink by mouth and afterwards rest.

When signs of hypoglycemia have disappeared or when blood sugar levels are controlled, continue Ripalid treatment.

You should tell people that are close to you that you have diabetes and that if you pass out (become unconscious) due to a 'hypo', you should be laid turned on the side, and immediately get medical assistance. You should not be given any food or drink if you are unconscious in order to prevent choking.

- If severe hypoglycemia is not treated, it may cause brain damage (temporary or permanent) and even death.
- If you suffer from hypoglycemia that makes you pass out, or from many incidents of hypoglycemia, talk to your doctor. It may be necessary to change the dosage of Ripalid, or make a change in diet or exercise.

❗ If the sugar level in your blood rises:

The blood sugar level may get too high (hyperglycemia). Hyperglycemia can be caused:

- If you take too low a dose of Ripalid.
- If you have an infection or a fever.
- If you eat more than usual.
- If you exercise less than usual.

The warning signs of hyperglycemia appear gradually and include: increased urination, thirst, dry skin and dry mouth. Talk to your doctor. It may be necessary to change the dosage of Ripalid, or to make a change in diet or exercise.

❗ Drug interactions

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

Other medicines and Ripalid

Especially inform the doctor or pharmacist if you are taking other medicines. You can take Ripalid with metformin, another medicine for treating diabetes, if the doctor prescribes it.

If you take gemfibrozil (a medicine to lower fat levels in the blood), you should not take Ripalid.

Your body's response to treatment with Ripalid may change if you use other medicines, such as:

- Medicine from the monoamine oxidase inhibitors (MAOI) group used to treat depression.
- Beta blockers (used to treat certain heart conditions and hypertension).
- ACE-inhibitors (used to treat certain heart conditions).
- Salicylates (e.g., aspirin).
- Octreotide (used to treat cancer).
- Nonsteroidal anti-inflammatory drugs (NSAIDs, a type of painkillers).
- Steroids, anabolic steroids and corticosteroids – to treat anaemia or inflammation.
- Oral contraceptives.
- Diuretics (thiazides).
- Danazol (used to treat breast cysts or endometriosis).
- Medicines containing thyroid hormones (to treat low levels of thyroid hormones).
- Sympathomimetics to treat asthma.
- Clarithromycin, trimethoprim, rifampicin (antibiotic medicines).
- Itraconazole, ketoconazole (antifungal medicines).
- Ciclosporin (to suppress the immune system).
- Deferasirox (to reduce circulating blood iron levels).
- Clopidogrel (to prevent blood clots).
- Phenytoin, carbamazepine, phenobarbital (to treat epilepsy).
- *Hypericum* (St. John's wort) (a herb).

❗ Taking Ripalid and food

Take Ripalid before the main meals.

❗ Use of Ripalid and alcohol consumption

Alcohol can change the ability of Ripalid to reduce the blood sugar levels. Pay attention to signs of a 'hypo' mentioned above.

❗ Pregnancy and breastfeeding

If you are pregnant, breastfeeding or think you are pregnant or plan to become pregnant, consult with your doctor before taking the medicine. Do not take Ripalid if you are pregnant or plan to become pregnant. Do not take Ripalid if you are breastfeeding.

If any of the above-listed conditions apply to you, **tell the doctor or pharmacist** and do not take Ripalid.

❗ Driving and using machinery

Your ability to drive or use machinery may be affected if your blood sugar level is low or high. Bear in mind that you could endanger yourself or other people. You should consult with your doctor whether you can drive a car in the following cases:

- If you suffer from frequent hypoglycemia incidents.
- If your warning signs of hypoglycemia are reduced or non-existent.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure. The dosage will be determined by your doctor.

- **The usual starting dosage** is 0.5 mg before each main meal. Take the tablets with a glass of water immediately before or up to 30 minutes before each main meal.

- The tablet should be swallowed whole. There is no information regarding halving or crushing the tablet.

- The dosage will be adjusted by your doctor, up to a dosage of 4 mg, to be taken with a glass of water immediately before or up to 30 minutes before each main meal. The maximum recommended daily dose is 16 mg. **Do not exceed the recommended dose.**

Do not take more tablets than the doctor has recommended for you. Always adhere to the treatment with Ripalid as recommended by the doctor. **If you have additional questions regarding use of Ripalid, consult the doctor or pharmacist.**

If you take too many tablets, your blood sugar level may become too low, leading to a 'hypo'. See section 2 "If you experience a 'hypo'" for an explanation of this condition and how to treat it.

If you accidentally take a higher dose or if anyone has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

❗ If you forget to take the medicine

If you forget to take this medicine at the required time, never take a double dose. Take the next dose as usual.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

❗ If you stop taking Ripalid

You should know that the desired effect is not achieved and the condition of your diabetes may get worse. If any change in the treatment is necessary, consult the doctor first.

If you have additional questions regarding the use of Ripalid, ask the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ripalid 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.

Hypoglycemia

The most frequent side effect is hypoglycemia which may affect up to 1 patient in 10 patients (see in section 2 "If you experience a 'hypo'"). Hypoglycemic reactions are generally mild to moderate, but may occasionally develop into hypoglycemic unconsciousness or coma. In this case, get medical assistance immediately!

Allergy

Allergy is very rare (may affect up to 1 patient in 10,000 patients). Signs such as swelling, difficulty in breathing, rapid heartbeat, dizziness and sweating – all these could be signs of an anaphylactic reaction. Contact a doctor immediately!

Other side effects

Common side effects (appear in frequency of up to 1 user in 10):

Stomach pain, diarrhea.

Rare side effects (appear in frequency of up to 1 user in 1,000):

Acute coronary heart disease (not necessarily due to the medicine).

Very rare side effects (appear in frequency of up to 1 user in 10,000):

Vomiting, constipation, blurry vision, severe liver problems, abnormal liver function, increased liver enzymes in the blood.

Side effects appearing with unknown frequency

Hypersensitivity (such as rash, itchy skin, reddening of the skin, swelling of the skin); nausea.

If a side effect occurs, if any of the side effects worsen or when 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 following link:

<https://sideeffects.health.gov.il>

Additionally, you can report to Padagis via the following address: padagis.co.il

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 and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

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

Do not use the medicine after the expiry date (exp. date) that appears on the carton package and blister package. The expiry date refers to the last day of that month.

Store in the original package below 25°C.

Do not discard medicines via wastewater or household waste. Ask the pharmacist how to discard medicines you no longer need. Taking these measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains the following inactive ingredients: Microcrystalline cellulose, Maize starch, Calcium hydrogen phosphate anhydrous, Polacrillin potassium, Meglumine, Poloxamer, Magnesium stearate, Povidone, Glycerol anhydrous
 - Ripalid 1 mg also contains Yellow iron oxide
 - Ripalid 2 mg also contains Red iron oxide
 - Ripalid 0.5 mg tablet is round and colored white.
 - Ripalid 1 mg tablet is round and colored yellow.
 - Ripalid 2 mg tablet is round and colored red.
- The tablets are packaged in trays (blisters) in packs of 30, 90 or 120 tablets.
- Registration holder and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
 - Manufacturer's name and address: Rivopharm S.A., Manno, Switzerland
 - Revised in September 2022 according to MOH guidelines.
 - Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Ripalid 0.5 mg: 15905.34990
Ripalid 1 mg: 15817.33936
Ripalid 2 mg: 15818.33935