

Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

NovoNorm 0.5 mg
NovoNorm 1 mg
NovoNorm 2 mg

Tablets

Active ingredient:

Each 0.5 mg tablet (white) contains 0.5 mg repaglinide.

Each 1 mg tablet (yellow) contains 1 mg repaglinide.

Each 2 mg tablet (orange) contains 2 mg repaglinide.

Inactive ingredients and allergens: see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine.

If you have any further questions, consult your doctor or pharmacist.

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

This medicine is not intended for adolescents under 18 years and adults over 75.

1. What is this medicine intended for?

NovoNorm is an oral antidiabetic medicine containing repaglinide which helps your pancreas produce more insulin and thereby lower your blood sugar (glucose).

Type 2 diabetes is a disease in which your pancreas does not make enough insulin to control the sugar level in your blood or where your body does not respond normally to the insulin it produces.

NovoNorm is used to treat type 2 diabetes in adults as an add-on to diet and exercise:

Treatment is usually started if diet, weight reduction, or exercise alone do not control or lower your blood sugar. NovoNorm treatment can be combined with metformin, another medicine for diabetes.

NovoNorm has been shown to effectively lower blood sugar level, which helps to prevent complications from your diabetes.

Therapeutic group: meglitinides for treating diabetes.

2. Before using this medicine

Do not use this medicine if:

- you are **sensitive** (allergic) to repaglinide or to any of the other ingredients in this medicine (see section 6).
- you have type 1 diabetes.
- the acid level in your blood is high (ketoacidosis, diabetic ketoacidosis)
- you have a severe liver disease.
- you take gemfibrozil (a medicine used to lower high levels of fat in the blood)
- you are pregnant or breast-feeding.

Special warnings about using this medicine

Before treatment with NovoNorm, tell your doctor if:

- you have liver problems. NovoNorm is not recommended in patients with mild to moderate liver disease. Do not take NovoNorm if you have a severe liver disease (see under 'Do not use this medicine if').
- you have kidney problems. NovoNorm should be taken with caution.
- you are about to have major surgery or you have recently suffered a severe illness or infection. In all these cases, diabetic control could be disturbed.
- you are under 18 or over 75 years old. NovoNorm is not recommended. There are no studies of treatment in these age groups.

Talk to your doctor if any of the conditions above apply to you. Treatment with NovoNorm may not be suitable for you. Your doctor will advise you.

Children and adolescents

Do not take this medicine if you are under 18 years old.

If you get hypoglycaemia (low blood sugar)

You may get hypoglycaemia if your blood sugar gets too low. This may happen:

- if you take too much NovoNorm
- if you exercise more than usual
- if you take other medicines or suffer from liver or kidney problems (see section 2 under 'Special warnings about using this medicine')

The warning signs of hypoglycaemia may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heart beat; nausea; feeling very hungry; temporary changes in vision; drowsiness; extreme tiredness and weakness; nervousness or tremor; anxiety; confusion; difficulty in concentrating.

If your blood sugar is low or you feel hypoglycaemia coming on you should eat sugar tablets or a high sugar snack or drink, then rest.

When symptoms of hypoglycaemia have disappeared or when blood sugar levels are stabilised, continue NovoNorm treatment.

Tell people you have diabetes and that if you pass out (become unconscious) due to hypoglycaemia, they must turn you on your side and get medical help immediately. They must not give you food or drink if you are unconscious. It could choke you.

- **If severe hypoglycaemia** is not treated, it can cause brain damage (temporary or permanent) and even death.

- **If you have hypoglycaemia** that makes you pass out or many hypoglycaemia events, talk to your doctor. The amount of NovoNorm, diet, or exercise may need to be adjusted.

If your blood sugar gets too high:

Your blood sugar may get too high (hyperglycaemia). This may happen:

- if you take too little NovoNorm
- if you have an infection or a fever
- if you eat more than usual
- if you exercise less than usual.

The warning signs of blood sugar that is too high appear gradually. They include: increased urination; thirst; dry skin and dry mouth. Talk to your doctor. The amount of NovoNorm, diet, or exercise may need to be adjusted.

Drug interactions

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

- You can take NovoNorm with metformin, another medicine for diabetes, if your doctor prescribes it.
- If you take gemfibrozil (used to lower high levels of fat in the blood), do not take NovoNorm.

Your body's response to NovoNorm may change if you take other medicines, especially these medicines:

- monoamine oxidase inhibitors (MAOI) (used to treat depression)
- beta blockers (used to treat certain heart conditions and high blood pressure)
- ACE-inhibitors (used to treat certain heart conditions)
- salicylates (such as aspirin)
- octreotide (used to treat cancer)
- nonsteroidal anti-inflammatory drugs (NSAIDs) (a type of painkillers)
- steroids (anabolic steroids and corticosteroids – used to treat anaemia or inflammation)
- birth control pills
- thiazides (diuretics)
- danazol (used to treat breast cysts and endometriosis)
- thyroid products (used to treat low levels of thyroid hormones)
- sympathomimetics (used to treat asthma)
- clarithromycin, trimethoprim, rifampicin (antibiotic medicines)
- itraconazole, ketoconazole (antifungal medicines)
- ciclosporin (used to suppress the immune system)
- deferasirox (used to reduce chronic iron overload)
- clopidogrel (prevents blood clots)
- phenytoin, carbamazepine, phenobarbital (used to treat epilepsy)
- Hypericum (St. John's wort) (herbal remedy).

Using this medicine and alcohol consumption

Alcohol can change the ability of NovoNorm to lower your blood sugar. Watch for signs of hypoglycaemia.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not use NovoNorm if you are pregnant or are planning to have a baby.

Do not use NovoNorm if you are breast-feeding.

Driving and using machines

Your ability to drive or use machines may be affected if your blood sugar is low or high. Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car if:

- you have frequent hypoglycaemia episodes
- you have few or no warning signs of hypoglycaemia.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

- **The usual starting dose** is 0.5 mg before each main meal. Swallow the tablets with a glass of water immediately before or up to 30 minutes before each main meal.
- Your doctor will adjust your dose up to a dose of 4 mg to be taken 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 crush/split/chew, because this may cause the tablet to crumble and affect the accuracy of your dose.

If you have accidentally taken a higher dose

If you take too many tablets your blood sugar may become so low that you get hypoglycaemia. See the section 'If you get hypoglycaemia' for an explanation of what hypoglycaemia is and how to treat the condition.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take the medicine at the scheduled time, do not take a double dose.

Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine

Be aware that the desired effect is not achieved if you stop using NovoNorm. Your diabetes may get worse. If any change of treatment is necessary contact your doctor first.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using NovoNorm may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them. The following side effects may happen with this medicine:

Hypoglycaemia

The most frequent side effect is hypoglycaemia which may affect up to 1 in 10 patients (see section 2 under 'If you get hypoglycaemia'). Hypoglycaemic reactions are generally mild/moderate but may occasionally develop into hypoglycaemic unconsciousness or coma. If this reaction happens, medical assistance is needed immediately.

Allergy

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

Additional side effects

Common side effects (may affect up to 1 in 10 patients):

- stomach pain
- diarrhoea.

Rare side effects (may affect up to 1 in 1,000 patients):

- acute coronary heart disease (not necessarily related to the medicine).

Very rare side effects (may affect up to 1 in 10,000 patients):

- vomiting
- constipation
- blurred vision
- severe problems with liver function, abnormal liver function such as increased level of liver enzymes in your blood.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- hypersensitivity (such as rash, itchy skin, reddening of the skin, swelling of the skin)
- nausea.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the blister label and the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Store in the original package to protect from moisture.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

calcium hydrogen phosphate anhydrous, microcrystalline cellulose, maize/corn (dried) starch, polacrillin potassium, povidone, glycerol 85%, magnesium stearate, meglumine, poloxamer 188.

NovoNorm 1 mg tablet: contains iron oxide yellow

NovoNorm 2 mg tablet: contains red iron oxide

What the medicine looks like and contents of the pack:

NovoNorm tablets are round and convex and debossed with the Novo Nordisk logo (Apis bull). The tablets are available in strengths of 0.5 mg (white tablets), 1 mg (yellow tablets), and 2 mg (orange tablets). Packs contain 30, 90, or 120 tablets. Not all pack sizes may be marketed.

Registration holder's name and address:

Novo Nordisk Ltd.
1 Atir Yeda St.,
Kfar Saba 4464301

Manufacturer's name and address:

Novo Nordisk A/S
Novo Allé, DK-2880 Bagsværd,
Denmark

This leaflet was approved in December 2015.

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

NovoNorm 0.5 mg: 114 47 29661
NovoNorm 1 mg: 114 48 29662

NovoNorm 2 mg: 114 49 29663

Novonorm IL PIL DEC15 V.2