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**PATIENT PACKAGE INSERT 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

## The active ingredients:

Each tablet of 0.5 mg (white) contains Repaglinide 0.5 mg

Each tablet of 1 mg (yellow) contains Repaglinide 1 mg

Each tablet of 2 mg (peach-coloured) contains Repaglinide 2 mg

**Inactive ingredients in the preparation:** see section 6 - Further information.

**Read all of this leaflet carefully before you start taking this medicine**, because it contains concise information on the medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- This medicine is not intended neither for adolescents below the age of 18 years, nor for adults above 75 years of age.

## What is in this leaflet

1. What is this medicine intended for?
2. Before using the medicine
3. How to use the medicine?
4. Side effects
5. How to store the medicine?
6. Further information

## 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 control type 2 diabetes in adults as an add-on to diet and exercise: treatment is usually started if diet, exercise and weight reduction alone have not been able to control (or lower) your blood sugar level. NovoNorm® can also be given with metformin, another medicine for diabetes.

NovoNorm® has been shown effectiveness in lowering the blood sugar level, which helps to prevent complications from your diabetes.

**Therapeutic group:** Medicines for the treatment of diabetes from the Meglitinide family.

## 2. Before using the medicine

### Do not take the medicine if:

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

### Special warnings regarding the use of this medicine

Talk to your doctor before taking NovoNorm®:

- If you have **liver problems**. NovoNorm® is not recommended in patients with moderate liver disease. NovoNorm® should not be taken if you have a severe liver disease (see *Do not take the medicine if*).
- If you have **kidney problems**. NovoNorm® should be taken with caution.
- If you are about to have **major surgery** or you have recently suffered from a **severe illness or infection**. At such times diabetic control may be lost.
- If you are **under 18 or over 75 years of age**, NovoNorm® is not recommended. It has not been studied in these age groups.

**Talk to your doctor** if any of the above applies to you. 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 of age.

### If you get a hypo (low blood sugar level)

You may get a hypo (short for 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 other sections of 2. *Before using the medicine*).

**The warning signs of a hypo** may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heart beat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

**If your blood sugar is low or you feel a hypo coming on:** eat glucose 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 a hypo, they must turn you on your side and get medical help straight away. They must not give you any food or drink. It could choke you.

- If **severe hypoglycaemia** is not treated, it can cause brain damage (temporary or permanent) and even death.
- If **you have a hypo** that makes you pass out, or a lot of hypos, talk to your doctor. The amount of NovoNorm®, food 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 too high blood sugar** appear gradually. They include: increased urination; feeling thirsty; dry skin and dry mouth. Talk to your doctor. The amount of NovoNorm®, food or exercise may need to be adjusted.

### Other medicines and NovoNorm®

**If you are taking or if you have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the 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 increased fat levels in the blood) you should not take NovoNorm®.

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

- Monoamine oxidase inhibitors (MAOI) (used to treat depression)
- Beta blockers (used to treat high blood pressure or heart conditions)
- ACE-inhibitors (used to treat heart conditions)
- Salicylates (e.g. aspirin)
- Octreotide (used to treat cancer)

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- Nonsteroidal anti-inflammatory drugs (NSAID) (a type of painkillers)
- Steroids (anabolic steroids and corticosteroids – used for anemia or to treat inflammation)
- Oral contraceptives (birth control pills)
- Thiazides (diuretics or 'water pills')
- 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, ketokonazole (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)
- St. John's wort (herbal medicine).

**Inform your doctor or pharmacist especially if you take one of the above medicines.**

### Use of the medicine and alcohol consumption

Alcohol can change the ability of NovoNorm® to reduce the blood sugar. Watch for signs of a hypo.

### 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.

You should not take NovoNorm® if you are pregnant or you are planning to become pregnant.

You should not take NovoNorm® if you are breast-feeding.

### Driving and using machines

Your ability to drive or use a machine 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 hypos
- Have few or no warning signs of hypos.

## 3. How to use the medicine?

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure. The dose and way of treatment will be determined by the doctor only.

- **The normal 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.
- The dose may be adjusted by your doctor by up to 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/cut/chew the tablet, as this action might crumble the tablet and cause dosage inaccuracy.

### If you accidentally took a higher dose

If you take too many tablets, your blood sugar may become too low, leading to a hypo. Please see *If you get a hypo* on what a hypo is and how to treat it. If you took an overdose, or if a child 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 miss a dose, take the next dose as usual - do not double the dose.

Adhere to the treatment as recommended by the doctor.

Do not stop the treatment without consulting your doctor, even if there is an improvement in your health situation.

### If you stop taking the medicine

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

### How can you contribute to the successful of the treatment?

You have to persist with the treatment as your doctor recommended.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Side effects

As with any medicines, the use of NovoNorm® 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.

### Hypoglycaemia

The most frequent side effect is hypoglycaemia, which may affect up to 1 in 10 patients (see *If you get a hypo* in section 2). Hypoglycaemic reactions are generally mild/moderate but may occasionally develop into hypoglycaemic unconsciousness or coma. If this 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, feeling dizzy and sweating could be signs of anaphylactic reaction. Contact a doctor immediately.

### Other side effects

**Common** (may affect up to 1 in 10 patients)

- Stomach pain
- Diarrhoea.

**Rare** (may affect up to 1 in 1,000 patients)

- Acute coronary syndrome (but it may not be due to the medicine).

**Very rare** (may affect up to 1 in 10,000 patients)

- Vomiting
- Constipation
- Visual disturbances
- Severe liver problems, abnormal liver function such as increased liver enzymes in your blood.

### Frequency not known

 (frequency not yet determined)

- Hypersensitivity (such as rash, itchy skin, reddening of the skin, swelling of the skin)
- Feeling sick (nausea).

If you get any side effect, if any of the side effects worsen or if you suffer from a side effect not listed in this leaflet, consult with your doctor

### Reporting of side effects

Reporting side effects to the ministry of health is possible by clicking the link "report side effects of drug treatment", listed at the MoH website ([www.health.gov.il](http://www.health.gov.il)), which refers to a form for this matter or via the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

## 5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not cause vomiting without explicit instruction from your doctor.
- Do not use this medicine after the expiry date, which is stated on the carton and the blister foil after EXP. The expiry date refers to the last day of that month.
- Store below 25°C.
- Store in the original package, in order to protect from moisture.
- Do not throw away any 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. Further information

**In addition to the active substance, the medicine also contains:**

Microcrystalline cellulose, calcium hydrogen phosphate anhydrous, maize starch, polacrillin potassium, povidone, glycerol 85%, magnesium stearate, meglumine, poloxamer.

NovoNorm® 1 mg tablet contains iron oxide yellow

NovoNorm® 2 mg tablet contains iron oxide red

### What the medicine looks like and contents of the pack:

NovoNorm® tablets are round and convex and engraved with the Novo Nordisk logo (Apis bull). The strengths are 0.5 mg, 1 mg and 2 mg.

0.5 mg tablets are white, 1 mg tablets are yellow and 2 mg tablets are peach-coloured. Each pack contains 30, 90, 120 or 270 tablets. Not all pack sizes may be marketed.

**License holder and address:**

Novo Nordisk Ltd.  
20 Hata'as St., Industrial Zone  
Kfar Saba 4442520

**Manufacturer name and address:**

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

This leaflet was checked and approved by the Ministry of Health in December 2015.

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

NovoNorm® 0.5 mg	114 47 29661
NovoNorm® 1 mg	114 48 29662
NovoNorm® 2 mg	114 49 29663

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