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What NovoNorm® is used for

NovoNorm® is used to control type 2 diabetes 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. NovoNorm® can also be given with metformin.

How NovoNorm® works

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

Before you use NovoNorm®

-When you must not use it

- If you are **hypersensitive** (allergic) to repaglinide or any of the other components of the medicine
- If you have **type 1 diabetes** (*insulin-dependent diabetes*)
- If the acid level in your body is raised (**ketoacidosis**)
- If you have a **severe liver disease**
- If you take **gemfibrozil** (a medicine used to lower increased fat levels in the blood).

If any of these apply to you, **tell your doctor** and do not take NovoNorm®.

-Before you start to use it

- 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

- If you have **kidney problems**. NovoNorm® should be taken with caution
 - If you are about to have **major surgery** or you have recently suffered 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.

-Taking other medicines

You can take NovoNorm® with metformin 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)
- Nonsteroidal anti-inflammatory drugs (NSAID) (a type of painkillers)
- Steroids (anabolic steroids and corticosteroids – 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, ketoconazole (antifungal medicines)

- Gemfibrozil (used to treat high blood fats)
- Ciclosporin (used to suppress the immune system)
- Phenytoin, carbamazepine, phenobarbital (used to treat epilepsy)

Tell your doctor if you have recently taken any of these medicines, or any medicines obtained without a prescription.

How to use NovoNorm®

-How much to use

Your doctor will work out your dose.

- **The normal starting dose** is 0.5 mg before each main meal.
- The dose may be adjusted by your doctor by up to 4 mg.
- The maximum recommended daily dose is 16 mg.

Do not take more NovoNorm® than your doctor has recommended. Always take NovoNorm® exactly as your doctor has told you. Check with your doctor if you are not sure.

-When to use it

Swallow the tablets with a glass of water immediately before or up to 30 minutes before each main meal.

-How long to use it

Use NovoNorm® until your doctor tells you to stop if a change of your treatment is necessary.

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

-If you forget to use it

If you miss a dose, take the next dose as usual - do not double the dose.

-If you use too much (overdose)

If you take too many tablets, your blood sugar may become too low, leading to a hypo.

While you are using it

-Things you must do

Take NovoNorm® before main meals. Alcohol can change the

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

-Things you must not do

You should not take NovoNorm® if you are pregnant or you are planning to become pregnant. See your doctor as soon as possible if you become pregnant or are planning to become pregnant during treatment. You should not take NovoNorm® if you are breast-feeding.

-Things to be careful of

Your ability to drive or operate 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.

Side effects

Like all medicines, NovoNorm® can cause side effects, although not everybody gets them.

Possible side effects

Common (may affect up to 1 in 10 patients)

- Hypoglycaemia. The risk of getting a hypo may increase if you take other medicines (see *Taking other medicines*)
- Stomach pain
- Diarrhoea.

Rare (may affect up to 1 in 1000 patients)

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

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

- Allergy (such as swelling, difficulty in breathing, rapid heart beat, feeling dizzy, sweating, which could be signs of anaphylactic reaction). Contact a doctor immediately
- Vomiting
- Constipation
- Visual disturbances

- Severe liver problems, abnormal liver function, increased liver enzymes in your blood.

Frequency unknown

- Hypoglycaemic coma or unconsciousness. Contact a doctor immediately
- Hypersensitivity (such as rash, itchy skin, reddening of the skin, swelling of the skin)
- Feeling sick (nausea).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of NovoNorm®

-Storage

Store in a dry place at 15°C - 25°C in order to protect from moisture. Store in the original package.

Keep out of the reach and sight of children.

-Disposal

Do not use after the expiry date. The expiry date refers to the last date of that month. This is stated on the outer carton and the blister foil. Medicines should not be disposed of down the drain or in household rubbish. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

NovoNorm® tablets are round and convex and engraved with the Novo Nordisk logo (Apis bull). 1 mg tablets are yellow and 2 mg tablets are peach-coloured.

-Ingredients

-Active ingredient
repaglinide.

-Inactive ingredients

Cellulose, microcrystalline (E460); calcium hydrogen phosphate, anhydrous; maize starch; polacrillin potassium; povidone K25; glycerol; magnesium stearate; meglumine; poloxamer 188; iron oxide yellow (E172) only in the 1 mg tablets and iron oxide red (E172) only in the 2 mg tablets.

-MAL number:

MAL20001008AC (1mg)
MAL20001009AC (2mg)

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG Binger Strasse 173, 55216 Ingelheim am Rhein, Germany

Product Registration Holder

Novo Nordisk Pharma (M) Sdn Bhd Unit A-9-2, Level 9, Tower A Menara UOA Bangsar No.5 Jalan Bangsar Utama 1 59000 Kuala Lumpur, Malaysia

Date of revision

23/6/2014