APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

NovoNorm® 0,5 mg Tablets

NovoNorm® 1,0 mg Tablets

NovoNorm® 2,0 mg Tablets

Read all of this leaflet carefully before you start taking/using/are given NovoNorm®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- NovoNorm has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT NovoNorm® CONTAINS:

The active substance ingredient contained in NovoNorm® is repaglinide.

NovoNorm® 0,5 mg contains 0,5mg repaglinide.

NovoNorm® 1,0 mg contains 1 mg repaglinide.

NovoNorm® 2,0 mg contains 2 mg repaglinide.

The other ingredients are amberlite (polacrilin potassium); calcium hydrogen phosphate, anhydrous; glycerol 85 %; magnesium stearate; maize starch; meglumine; microcrystalline cellulose (E460); poloxamer and povidone (polyvidone).

NovoNorm® 1,0 mg tablets also contain iron oxide yellow (E172) as a colour pigment.

NovoNorm® 2,0 mg tablets also contain iron oxide red (E172) as a colour pigment.

WHAT NovoNorm® IS USED FOR:

NovoNorm® helps your pancreas to produce more insulin in relation to meals, and is used to control your diabetes. Treatment of Type 2 diabetes with NovoNorm® is an adjunct to diet and exercise.

Treatment with NovoNorm® should begin if diet, exercise and weight reduction alone have not been able to control (or lower) your blood glucose levels. NovoNorm® can also be given with metformin or other medicines for diabetes.

BEFORE YOU TAKE NovoNorm®:

Do not take NovoNorm® if:

- You have been told you are allergic to repaglinide or any of the inactive ingredients in NovoNorm®;
- You have Type 1 diabetes (Juvenile Insulin Dependent Diabetes Mellitus) ;
- The acid level in your body is raised (diabetic ketoacidosis);
- You are under 18 years of age;
- You have severe kidney or liver disease;
- You are pregnant or breastfeeding;
- You use gemfibrozil (a medicine used to lower increased fat levels in the blood) as this may cause a strong enhancement and prolongation of the effect of NovoNorm®. Please be sure to inform your doctor if you use gemfibrozil.
- You use deferasirox (a medicine used to treat chronic blood iron overload) as this may cause a strong enhancement and prolongation of the effect of NovoNorm®. Please be sure to inform your doctor if you use deferasirox.
- You use clopidogrel (a medicine used to prevent blood clots) as this may cause a strong enhancement and prolongation of the effect of NovoNorm®. Please be sure to inform your doctor if you use clopidogrel.

- You are a child.
- You are pregnant of breastfeeding.

Take special care with NovoNorm®:

NovoNorm® should be prescribed to you if poor blood glucose control and symptoms of diabetes persist despite diet, exercise and weight reduction.

Low blood sugar reactions have been observed after taking NovoNorm®.

The symptoms of low blood sugar may include feeling anxious, dizziness, sweating, tremour, hunger and difficulty in concentration.

Low blood sugar may be treated by eating food containing sugars. Severe low blood sugar will require that glucose be injected into your vein by a health care professional.

Tell your doctor or healthcare professional if:

- You have liver or kidney problems;
- You are about to have major surgery or you have recently suffered a severe illness or infection.

Pregnancy and Breastfeeding:

- NovoNorm® should not be used if you are pregnant or you are planning to become pregnant.
- NovoNorm® should not be used if you are breastfeeding your baby.

If you are pregnant or breast feeding your baby while taking NovoNorm® , please consult your doctor, pharmacist or other health care professional for advice before taking NovoNorm® .

Driving and Using Machinery:

You are advised to take precautions to avoid low blood sugar whilst driving and using machinery. This is particularly important if you have reduced or absent awareness of the warning signs of low blood sugar or if you have frequent episodes of low blood sugar. The advisability of driving and using machinery should be considered in these circumstances.

Taking NovoNorm® with other medicines:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

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);
- Angiotensin Converting Enzyme (ACE) inhibitors and Angiotensin
- Receptor Blockers (ARBs) - (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 – used for anaemia or to treat inflammation);
- Alcohol;
- 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);
- Deferasirox (used to reduce chronic iron overload);
- Clopidogrel (prevents blood clots)
- Phenytoin, carbamazepine, phenobarbital (used to treat epilepsy).

HOW TO TAKE NovoNorm®:

Do not share medicines prescribed for you with any other person.

Always take NovoNorm® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

You should take your NovoNorm® before each main meal. Tablets should be swallowed with a glass of water. Your doctor will determine your starting dose. A normal starting dose is 0,5 mg taken just before each main meal. The dose may be adjusted by your doctor up to 4 mg before a main meal. The maximum recommended daily dose is 16 mg.

Your doctor will tell you how long your treatment with NovoNorm® will last. Do not stop treatment early. If you have the impression that NovoNorm® is too strong or too weak, tell your doctor or pharmacist. Your doctor may prescribe NovoNorm® in combination with metformin or other medicines for diabetes.

NovoNorm® has not been studied in patients under 18 years of age or above 75 years of age. The use of NovoNorm® is not recommended in these patients.

NovoNorm® has not been studied in patients with moderate to severe liver or kidney disease. The use of NovoNorm® is not recommended in these patients.

If you take more NovoNorm® than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take/missed a dose of NovoNorm®:

If you forget to take a dose, take the next dose as usual. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

NovoNorm® can have side-effects.

Interactions with other medicinal products may increase the risk of low blood sugar. If you have an overdose of NovoNorm®, your blood sugar may become too low. Symptoms of too low blood sugar include:

- Headache;
- Dizziness;
- Tiredness;
- Rapid heartbeat;
- Nervousness and shakiness;
- Nausea;
- Sweating.

If you experience any of these symptoms, you should take glucose tablets or sugar or take a sugary drink and then rest. If you are worse, contact your doctor or nearest hospital emergency department at once.

If events of low blood sugar are not treated, they can be very serious and cause headaches, nausea, vomiting, dehydration, unconsciousness and even more serious conditions.

The other side-effects reported include visual disturbances, allergic reactions such as rash and itching and also gastrointestinal symptoms such as abdominal pain, nausea, diarrhoea, vomiting and constipation. Generalised hypersensitivity reaction (severe allergy) has been reported.

Increases in liver enzymes may occur.

Not all side-effects reported for NovoNorm® are included in this leaflet. Should your general health worsen while taking NovoNorm®, please consult your doctor, pharmacist or other health care professional for advice.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF NovoNorm®:

Store at or below 25°C. Protect from light/moisture.

Do not use it after the expiry date printed on the package.

KEEP OUT OF REACH OF CHILDREN.

PRESENTATION OF NovoNorm®:

Push-through aluminium/aluminium blister packs containing 30, 90, or 120 tablets.

IDENTIFICATION OF NovoNorm®:

NovoNorm® 0,5 mg: white, round, biconvex tablets, engraved with Novo Nordisk logo (Apis Bull).

NovoNorm® 1,0 mg: yellow, round, biconvex tablets, engraved with Novo Nordisk logo (Apis Bull).

NovoNorm® 2,0 mg: peach, round, biconvex tablets, engraved with Novo Nordisk logo (Apis Bull).

REGISTRATION NUMBERS OF NovoNorm®:

NovoNorm® 0,5 mg: 33/21.2/0078

NovoNorm® 1,0 mg: 33/21.2/0079

NovoNorm® 2,0 mg: 33/21.2/0080

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

Novo Nordisk (Pty) Ltd

150 Rivonia Road

10 Marion Street Office Park

Building C1, Sandton, Johannesburg

2196

DATE OF PUBLICATION

Date on the registration certificate: 06 September 1999

Date of the most recently revised package insert as approved by council:

11 December 2019