Package leaflet: Information for the user

Repaglinide STADA 0.5 mg tabletten
Repaglinide STADA 1 mg tabletten
Repaglinide STADA 2 mg tabletten
Repaglinide STADA 4 mg tabletten
Repaglinide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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.

What is in this leaflet
1. What Repaglinide STADA is and what it is used for
2. What you need to know before you take Repaglinide STADA
3. How to take Repaglinide STADA
4. Possible side effects
5. How to store Repaglinide STADA
6. Contents of the pack and other information

1. What REPAGLINIDE STADA is and what it is used for

Repaglinide STADA is an *oral antidiabetic agent* 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 in your blood or where your body does not respond normally to the insulin it produces (formerly known *as non-insulin-dependent diabetes mellitus or maturity onset diabetes*).

Repaglinide STADA 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. Repaglinide STADA can also be given with metformin, another medicine for diabetes.

2. What you need to know before you take REPAGLINIDE STADA

DO NOT take Repaglinide STADA:
- If you are allergic to repaglinide or any of the other ingredients of this medicine (listed in section 6.)
- If you have **type 1 diabetes** *(insulin-dependent diabetes)*
- If the acid level in your body is raised **(diabetic 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 Repaglinide STADA.

Warnings and precautions
Talk to your doctor or pharmacist before taking Repaglinide STADA. Especially if:

- You have **liver problems.** Repaglinide STADA is not recommended in patients with moderate liver disease. Repaglinide STADA should not be taken if you have a severe liver disease (see *DO NOT take Repaglinide STADA*).
- You have **kidney problems**. Repaglinide STADA should be taken with caution.
- 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.
- You are **under 18** or **over 75 years** of age. Repaglinide STADA is not recommended. It has not been studied in these age groups.

If you get a hypo
You may get a hypo (short for a hypoglycaemic reaction and is symptoms of low blood sugar) if your blood sugar gets too low. This may happen:
- If you take too much Repaglinide STADA
- If you exercise more than usual
- If you take other medicines or suffer from liver or kidney problems (see other sections of *2. What you need to know before you take Repaglinide STADA*).

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 Repaglinide STADA 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 Repaglinide STADA, 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 Repaglinide STADA
- If you have an infection or a fever
- If you eat more than usual
- If you exercise less than usual.

The warning signs appear gradually. They include: increased urination; feeling thirsty; dry skin and dry mouth. Talk to your doctor. The amount of Repaglinide STADA, food or exercise may need to be adjusted.

Other medicines and Repaglinide STADA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
You can take Repaglinide STADA 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 Repaglinide STADA.

Your body's response to Repaglinide STADA 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 - used for anaemia 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, 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)
- St. John’s wort (herbal medicine).

Repaglinide STADA with food, drink and alcohol
Take Repaglinide STADA before main meals. Alcohol can change the ability of Repaglinide STADA to reduce the blood sugar. Watch for signs of a hypo.

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

You should not take Repaglinide STADA 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 Repaglinide STADA if you are breast-feeding.

Driving and using machines
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.

Repaglinide STADA contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take REPAGLINIDE STADA

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will work out your dose.

- **The recommended 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.

Repaglinide STADA 4 mg tablets can be divided into equal doses.

Do not take more Repaglinide STADA than your doctor has recommended.

If you take more Repaglinide STADA than you should
If you take too many tablets, your blood sugar may become too low, leading to a hypo. Please see *If you get a hypo* of this leaflet on what a hypo is and how to treat it.

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

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)
- Hypoglycaemia (see *If you get a hypo* in section 2 of the leaflet). The risk of getting a hypo may increase if you take other medicines
- Stomach pain
- Diarrhoea.

Rare (may affect up to 1 in 1,000 people)
- Acute coronary syndrome (but it may not be due to the drug).

Very rare (may affect up to 1 in 10,000 people)
- 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 not known (frequency cannot be estimated from the available data)
- Hypoglycaemic coma or unconsciousness (very severe hypoglycaemic reactions - see *If you get a hypo*). Contact a doctor immediately
- Hypersensitivity (such as rash, itchy skin, reddening of the skin, swelling of the skin)
- Feeling sick (nausea).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store REPAGLINIDE STADA

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

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.

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. Contents of the pack and other information

What Repaglinide STADA contains

The active substance is Repaglinide.
Repaglinide STADA 0.5 mg, 1 mg, 2 mg and 4 mg
1 tablet contains either 0.5 mg, 1 mg, 2 mg or 4 mg Repaglinide.

The other ingredients are
Microcrystalline cellulose, Poloxamer 188, Croscarmellose sodium, Magnesium stearate.

What Repaglinide STADA looks like and contents of the pack

Repaglinide STADA 0.5 mg
White, round, 3.4 mm thick and biconvex tablets.
Repaglinide STADA 1 mg
White, round, 3.4 mm thick and biconvex tablets with embossment “1”.
Repaglinide STADA 2 mg
White, round, 4.2 mm thick and biconvex tablets with embossment “2”.
Repaglinide STADA 4 mg
White, round, 4.0 mm thick tablets with breaking notch on both sides.
Repaglinide STADA 4 mg tablets can be divided into equal halves.

Repaglinide STADA is available in packs containing 15, 30, 90, 120, 180 or 270 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder
STADA Arzneimittel AG
Stadastraße 2-18
D-61118 Bad Vilbel
Duitsland

Manufacturer*
STADA Arzneimittel AG, Stadastr. 2-18, D-61118 Bad Vilbel, Germany
Stada Arzneimittel GmbH, Muthgasse 36, 1190 Wien, Austria
Eurogenerics N.V., Heizel Esplanade B22, B-1020 Brussels, Belgium
LAMP SAN PROSPERO S.p.A., Via della Pace, 25/A, 41030 San Prospero (Modena), Italy

In het register ingeschreven onder
RVG 103352 - Repaglinide STADA 0,5 mg, tabletten
RVG 103355 - Repaglinide STADA 1 mg, tabletten
RVG 103356 - Repaglinide STADA 2 mg, tabletten
RVG 103357 - Repaglinide STADA 4 mg, tabletten

This medicinal product is authorised in the Member States of the EEA under the following names:

AT: Repaglinid Stada 0,5/1/2/4 mg - Tabletten
BE: Repaglinide EG 0,5/1/2/4 mg tabletten
BG: Indorin 0,5/1/2/4 mg tablets
DE: Repaglinid STADA 0,5/1/2 mg Tabletten
ES: Repaglinida STADA 0,5/1/2 mg comprimidos EFG
Repaglinida STADA 4 mg comprimidos
FI: Repaglinid STADA 0,5/1/2/4 mg tabletti
FR: REPAGLINIDE EG 0,5/1/2 mg, comprimé
IT: REPAGLINIDE EG 0,5/1/2 mg compresse
LU: Repaglinide EG 0,5/1/2/4 mg comprimés
RO: Repaglinidă HF 0,5/1/2/4 mg comprimate
SI: Repaglinid STADA 0,5/1/2/4 mg tablete
SE: Repaglinid STADA 0,5/1/2/4 mg tabletter
NL: Repaglinide STADA 0,5/1/2/4 mg, tabletten

Deze bijsluiter is voor de laatste keer goedgekeurd in juli 2022.

* in the printed package leaflet only the batch releaser which is/will be responsible for batch release of corresponding batch will be mentioned