

PACKAGE LEAFLET: INFORMATION FOR THE USER

Repa TAD® 0.5 mg tablets
Repa TAD® 1 mg tablets
Repa TAD® 2 mg tablets

Repaglinide

Read all of this leaflet carefully before you start taking this 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Repa TAD is and what it is used for
2. Before you take Repa TAD
3. How to take Repa TAD
4. Possible side effects
5. How to store Repa TAD
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1. What Repa TAD is and what it is used for

Repa TAD is an oral antidiabetic treatment medicine containing repaglinide which helps your pancreas produce more insulin and thereby lower blood sugar levels.

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*).

Repa TAD is used to control type 2 diabetes as add-on to diet and exercise: treatment is usually started if diet, exercise and weight loss alone have not been able to control (or lower) your blood sugar. Repa TAD can also be given in combination with metformin.

2. Before you take Repa TAD

Do not take Repa TAD

- if you are hypersensitive (allergic) to repaglinide or any of the other components of Repa TAD,
- if you have type 1 diabetes (insulin-dependent),
- 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 fat levels in the blood).

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

Take special care with Repa TAD

- if you have liver problems. Repa TAD is not recommended in patients with moderate liver disease. Repa TAD should not be taken if you have a severe liver disease (see *Do not take Repa TAD*).

- if you have kidney problems. Repa TAD 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. Repaglinide has not been studied in these age groups, therefore it is not recommended.

Talk to your doctor if any of the above applies to you. Repa TAD may not be suitable for you to use. Your doctor will advise you.

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 Repa TAD,
- if you exercise more than usual,
- if you take other medicines or suffer from liver or kidney problems (see other sections of 2. *Before you take Repa TAD*).

The warning signs of a hypo may come on suddenly and can include: cold sweat, cool pale skin, headache, rapid heartbeat, 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 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 Repa TAD, 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 Repa TAD,
- 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 Repa TAD, food or exercise may need to be adjusted.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you take gemfibrozil (used to lower increased fat levels in the blood) you should not take Repa TAD.

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

- Metformin, another anti-diabetic medicine leading to increased chances of low blood sugars.
- Monoamine oxidase inhibitors (used to treat depression).
- Non-selective beta blocking agents (used to treat high blood pressure and certain heart conditions).

- Angiotensin converting enzyme (ACE)-inhibitors (used to treat certain heart conditions).
- Salicylates (e.g. aspirin).
- Octreotide (used to treat cancer).
- Non-steroid anti-inflammatory drugs (NSAID, a painkiller).
- Steroids (anabolic steroids and corticosteroids – used for anaemia or to treat inflammation).
- Oral contraceptives (used for birth control).
- Thiazides (used to stimulate urine output).
- 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 medicine).
- Itraconazole, ketokonazole (antifungal medicines).
- Gemfibrozil (used to treat high blood fats).
- Ciclosporin (used to suppress the immune system).
- Phenytoin, carbamazepine, phenobarbital (used to treat epilepsy).
- St. John's wort (herbal medicine).

Taking Repa TAD with food and drink

Take Repa TAD before main meals. Alcohol can change the ability of Repa TAD to reduce the blood sugar. Watch for signs of a hypo.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You should not take Repa TAD 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 Repa TAD 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.

3. How to take Repa TAD

Your doctor will work out your dose.

- 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 take more Repa TAD than your doctor has recommended. Always take Repa TAD exactly as your doctor has told you. Check with your doctor if you are not sure.

If you take more Repa TAD than you should

If you take more tablets than you should, your blood sugar may become too low leading to a hypoglycaemic event. Please see *If you get a hypo* on what a hypo is and how to treat it.

If you forget to take Repa TAD

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

If you stop taking Repa TAD

Be aware that the desired effect is not achieved if you stop taking Repa TAD. Your diabetes may get worse. If any change is necessary it is absolutely important to contact your doctor first.

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

4. Possible side effects

Like all medicines, Repa TAD can cause side effects, although not everybody gets them.

Possible side effects

Common (affects 1 to 10 users in 100):

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

Rare (affects 1 to 10 users in 10,000):

- Acute coronary syndrome (sudden heart pain), but it may not be due to the drug

Very rare (affects less than 1 user in 10,000):

- Allergy (such as swelling, difficulty in breathing, rapid heartbeat, 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)

Not known (frequency cannot be estimated from the available data):

- Hypoglycaemic coma or unconsciousness (very severe hypoglycaemic reactions). A doctor should be contacted

immediately. See the section *Take special care* for symptoms and advice in *If you get a hypo* or low blood sugar.

- Hypersensitivity (such as rash, itchy skin, reddening of the skin, swelling of the skin; if this happens tell your doctor as soon as possible)
- 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 or pharmacist.

5. How to store Repa TAD

Keep out of the reach and sight of children.

Do not use Repa TAD after the expiry date which is stated on the blister and outer carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Repa TAD contains

- The active substance is repaglinide. Each tablet contains 0.5 mg, 1 mg, 2 mg repaglinide.
- The other ingredients are: microcrystalline cellulose (E460); calcium hydrogen phosphate, anhydrous; croscarmellose sodium; povidone K25; glycerol; magnesium stearate; meglumine; poloxamer; yellow iron oxide (E172) only in the 1 mg tablets and red iron oxide (E172) only in the 2 mg tablets

What Repa TAD looks like and contents of the pack

The 0.5 mg tablets are white, round and biconvex with bevelled edges.

The 1 mg tablets are pale brown-yellow, round, biconvex with bevelled edges and possible darker spots.

The 2 mg tablets are pink, marbled, round, biconvex with bevelled edges and possible darker spots.

Boxes of 90 tablets in blisters are available.

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