

Pharma code

Front

50 mm

Dimensions 160 x 270 mm



GB 675-0152-PIL

Package leaflet: Information for the user

Tolbutamide Tablets BP 500 mg

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

- Please 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 effect not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tolbutamide Tablets are and what they are used for
2. What you need to know before you take Tolbutamide Tablets
3. How to take Tolbutamide Tablets
4. Possible side effects
5. How to store Tolbutamide Tablets
6. Contents of the pack and other information

1. What Tolbutamide Tablets are and what they are used for

The name of your medicine is Tolbutamide Tablets BP 500 mg (referred to as Tolbutamide Tablets in this leaflet). Tolbutamide Tablets contain the active ingredient tolbutamide, which belongs to a group of medicines called oral hypoglycaemics.

Tolbutamide Tablets are used to treat mild to moderate diabetes of the non-insulin dependent type (type 2 or maturity onset diabetes), which does not respond to dietary measures. This usually only occurs in adults. Tolbutamide Tablets lower the sugar content in your blood if this is too high.

If you are overweight, treatment with Tolbutamide Tablets should not replace your dietary restrictions.

2. What you need to know before you take Tolbutamide Tablets

Do not take Tolbutamide Tablets

- if you are allergic to Tolbutamide Tablets or any of the other ingredients of this medicine (listed in section 6).
- if you have diabetes that needs to be treated by insulin (type 1 or insulin dependent diabetes)
- if you have ever had diabetic ketoacidosis (the symptoms of this include unusual smelling breath, drowsiness, confusion, feeling or being sick and difficulty breathing)
- if you have serious liver or kidney problems
- if you have serious problems with your adrenal or thyroid glands
- if you are under unusual stress
- if you need an operation
- if you are in the first trimester of pregnancy
- if you have an uncommon inherited blood disorder called porphyria
- if you are breast-feeding.

Warning and precautions

Talk to your doctor or pharmacist before taking Tolbutamide Tablets

- if you experience the symptoms of low blood sugar (such as sweating, pallor, hunger, faster heart beat and feeling unwell)
- if you are debilitated ('run down') or are elderly
- if you have had any problems taking medicines used to treat diabetes

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- if you have an infection, or the number of sore throats or fevers you experience increases or you develop spontaneous bruising or bleeding as your doctor may wish to test your blood
- if you have mild kidney disease
- if you have an inherited condition where your red blood cells do not produce enough of the enzyme G6PD (glucose 6 phosphate dehydrogenase).

Children

Tolbutamide Tablets are not for use in children.

Other medicines and Tolbutamide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines obtained without a prescription and herbal remedies.

This is especially important if you are taking any of the following:

- medicines which provide contraception e.g. oral contraceptives (the pill)
- medicines known as beta-blockers and thiazide diuretics which are used to treat a range of heart problems such as chest pain, irregular heartbeats heart failure or high blood pressure and generalised swelling (oedema)
- medicines used to prevent blood clotting e.g. warfarin, dicoumarol or coumarins
- a medicine used to suppress the immune system known as cyclophosphamide
- medicines known as corticosteroids e.g. prednisolone
- the antibiotics called chloramphenicol and rifampicin and antibiotics belonging to a group commonly known as sulphonamides such as sulfafurazole
- voriconazole, fluconazole and ketoconazole which are used to treat fungal infections
- a medicine called lithium which is used to treat mental depression
- monoamine oxidase inhibitors (MAOIs), for which you may carry a warning card and which are used to treat depression
- salicylates, e.g. aspirin used to treat pain
- adrenaline
- phenylbutazone (a non steroidal anti-inflammatory pain killer)

Tolbutamide Tablets with food and alcohol

Ask your doctor or pharmacist about your specific dietary requirements.

You are advised NOT to drink alcohol with this medicine.

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.

Driving and using machines

If you experience the symptoms of low blood sugar (hypoglycaemia), especially at the beginning of treatment, you should not drive or operate machinery.

3. How to take Tolbutamide Tablets

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

These tablets should be taken either with or immediately after the first main meal of the day or in smaller doses throughout the day with meals.

The recommended dose

Treatment of previously untreated diabetes: The initial starting dose is two tablets daily, but your doctor may advise you to increase or reduce this until he/she is satisfied that your blood sugar is properly under control. The usual daily dose is 1-3 tablets daily.

Change over from other oral hypoglycaemic (e.g. chlorpropamide): You can usually change between different oral hypoglycaemic drugs without a break in treatment. Initially, 1 g (2 tablets) is given. The maintenance dose will depend on response.

Change over from insulin: For some cases of non-insulin dependent diabetes, low insulin doses (less than 20 units) can be replaced immediately. With high insulin doses a gradual change is required. Insulin and tolbutamide will be given together, and the insulin dose will be gradually reduced.

Taking with biguanides: If you do not achieve adequate control of your diabetes through diet and 2 g (4 tablets) of tolbutamide daily then your doctor may also give you a biguanide drug, such as metformin, to help control your blood sugar levels.

Use in the elderly

If you are elderly, your doctor will initially prescribe a lower dose.

Use in children

Tolbutamide Tablets are not for use in children. The scoreline is not intended for breaking the tablet.

If you take more Tolbutamide Tablets than you should If you realize you have taken more Tolbutamide Tablets than your doctor has recommended (or if someone else has taken some of your Tolbutamide Tablets) contact your doctor right away. If you cannot reach your doctor go to your nearest hospital and take the pack with you.

An overdose of Tolbutamide Tablets could cause very low blood sugar level, which may make you feel very ill. Signs of an overdose include feeling or being sick, sweating, fast breathing or heart rate, low blood pressure or drowsiness.

If you forget to take Tolbutamide Tablets

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking Tolbutamide Tablets

You should continue to take this medicine for as long as your doctor tells you to otherwise your diabetes may not be controlled.

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.

Serious side effects

If the following symptoms occur, **please tell your doctor immediately.**

Symptoms of hypoglycaemia (low blood glucose levels):

- quickening of your heart rate
- sweating
- pallor
- feeling dizzy or hungry
- blurred vision
- inability to concentrate

Such symptoms are more common in elderly and debilitated patients.

Symptoms of allergic reactions:

- itching and/or rash
- swelling of face, lips, tongue and/or throat
- difficulty in swallowing
- difficulty breathing

If you feel very tired, experience unexpected bruising or bleeding, or more infections (e.g. colds and sore throats) than usual please tell your doctor. Your doctor may decide to conduct tests on your blood periodically as a result of these symptoms.

Other side effects

Other side effects may include:

- headache
- sensitivity to light, which may mean that your skin is more sensitive to the effects of the sun;
- tingling in hands or feet (pins and needles)
- feeling or being sick
- diarrhoea
- constipation
- increased or decreased appetite or weight gain
- skin or eyes appearing yellowish (jaundice)
- tinnitus
- an intolerance to alcohol, which may mean that alcohol affects you more than usual or makes you feel unwell.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Tolbutamide Tablets

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Keep in the original container or package in which they were packed in order to protect from light and moisture.

Do not use this medicine after the expiry date that is stated on the carton or bottle after EXP. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Tolbutamide Tablets contain

The active substance is tolbutamide. Each tablet contains 500 mg of tolbutamide. The other ingredients are: starch, povidone, sodium starch glycolate, stearic acid and magnesium stearate.

What Tolbutamide Tablets look like and the contents of the pack

Tolbutamide Tablets BP 500 mg are round, biconvex white tablets, marked on one side with "T" above a scoreline and "500" below it.

They are available in containers of 28, 50 and 500 and blister packs of 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR.

Manufacturer

Waymade Plc, Josselin Road, Burnt Mills Industrial Estate, Basildon, Essex, SS13 1QF.

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