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 Tolbutamide tablets are and what they are used for
Tolbutamide is one of a group of medicines called oral hypoglycaemics. These medicines are used to control blood sugar levels in some types of diabetes.

Tolbutamide tablets may be used to control blood sugar in patients with mild to moderate diabetes which cannot be controlled by diet alone.

Tolbutamide should only be used to treat diabetes which occurs mainly in adults (type 2 or non-insulin dependent diabetes).

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

Before you take Tolbutamide tablets
Do not take Tolbutamide tablets if you:
- have severe kidney, liver, thyroid or adrenal gland disease
- are experiencing unusual stress or are breast-feeding.
- need an operation
- suffer from a condition called porphyria (a hereditary disease affecting the liver or bone marrow).

Warnings and precautions
Tell your doctor or pharmacist before taking Tolbutamide tablets if:
- you are debilitated ("run down") or are elderly
- the number of sore throats or fevers you experience increases or you develop spontaneous bruising or bleeding. Your doctor may wish to test your blood
- you have mild kidney disease.
- have an inherited condition where your red blood cells don’t produce enough of the enzyme G6PD (glucose 6 phosphate dehydrogenase).

Children and adolescents
This medicine is not recommended for children and adolescents.

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

- medicines to treat high blood pressure such as beta blockers (e.g. propranolol, atenolol)
- adrenaline (epinephrine)
- antibiotics used to treat infections such as chloramphenicol, rifampicin or sulfonamides such as Sulfafurazole
- medicines used to prevent blood clotting (e.g. warfarin or dicumarol)
- medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs e.g. moclobemide)
- medicines used to treat mental health problems such as lithium
- corticosteroids used to reduce inflammation in the body (e.g. prednisolone)
- cyclophosphamide (used to treat some cancers)
- phenylbutazone (a non steroidal anti-inflammatory pain killer)
- diuretics (water tablets) such as bendroflumethiazide, hydrochlorothiazide
- the oral contraceptive pill
- salicylates (used for muscular or skeletal disorders e.g. aspirin)

Tolbutamide tablets and alcohol:
You are advised not to drink alcohol with this medicine. Discuss this with your doctor if you have any questions.

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 or pharmacist for advice before taking this medicine.
Driving and using machines:
Make sure your blood sugar levels are under control before you drive or operate machinery.

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

The recommended dose is
Untreated diabetes
Initially two tablets daily. The maintenance dose will depend upon your response to treatment; the usual daily dose is 1-3 tablets daily.

Change from other tablets
You can usually change between different diabetes tablets without a break in treatment. 2 tablets initially then maintenance dose will depend on response.

Change from insulin
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 4 tablets of tolbutamide daily then your doctor may also give you a biguanide drug, such as metformin, to help you control your blood sugar levels.

Elderly
If you are elderly your doctor may have initially started your treatment on a lower dose of tolbutamide.

Children
This medicine is not recommended for children and adolescents.

Swallow these tablets with or immediately after the first main meal of the day or in smaller doses throughout the day with meals. Take this medicine for as long as your doctor tells you to.

If you take more Tolbutamide tablets than you should:
If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include feeling or being sick, sweating, fast breathing or heart rate, low blood pressure, odd behaviour, drowsiness, fits or coma.

If you forget to take Tolbutamide tablets:
Take it as soon as you remember, unless it is nearly time for your next dose. Then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tolbutamide tablets:
Talk to your doctor before stopping treatment with this medicine.

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.

Stop taking Tolbutamide tablets and contact your doctor at once if you experience:
• An allergic reaction: skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing. This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
• Hypersensitivity effects: sensitivity to light, skin rashes.
• Blood: anaemia. Tolbutamide may change the number and type of cells in the blood, if you notice an increase in bruising or nose bleeds or in the number of sore throats or infections you are getting, tell your doctor.
• Metabolism: low blood sugar (sweating, shaking, double vision, slurred speech, confusion).
• Nervous system: headache, tingling (pins and needles).
• Ears: ringing in the ear.
• Stomach: feeling or being sick, diarrhoea, constipation, increased or decreased appetite or weight gain.
• Liver: jaundice (yellowing of the skin and/or eyes), changes in liver function (as seen in blood tests).
• Other effects: an intolerance to alcohol causing facial flushing.

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 out of the sight and reach of children. Store below 25°C in a dry place. Do not use this medicine after the expiry date stated on the carton 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 protect the environment.

6 Contents of the pack and other information
What Tolbutamide tablets contain
• The active substance is tolbutamide. Each tablet contains 500mg of tolbutamide.
• The other ingredients are maize starch, stearic acid, magnesium stearate, microcrystalline cellulose (E460).

What Tolbutamide tablets look like and contents of the pack
Tolbutamide tablets are white circular uncoated tablets which come in one strength. Pack sizes are 28 and 112.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK

This leaflet was last revised in August 2017

If you would like a leaflet with larger text, please contact 01271 311257.