

ARX-GLIMEPIRIDE Tablets

Glimepiride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ARX-GLIMEPIRIDE.

It does not contain all the available information. It does not take the place of talking to your doctor or, pharmacist

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ARX-GLIMEPIRIDE against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again

What ARX-GLIMEPIRIDE is used for

The name of your medicine is ARX-GLIMEPIRIDE. It contains the active ingredient glimepiride. ARX-GLIMEPIRIDE is used to control blood glucose in patients with type 2 diabetes mellitus.

ARX-GLIMEPIRIDE is used when healthy eating and increased physical activity are not enough to control your blood glucose.

ARX-GLIMEPIRIDE can be used alone, or together with insulin or other medicines for treating diabetes.

How it works

ARX-GLIMEPIRIDE lowers high blood glucose by increasing the

amount of insulin produced by your pancreas.

ARX-GLIMEPIRIDE tablets belong to a group of medicines called sulfonylureas.

If your blood glucose is not controlled properly, you may experience hypoglycaemia (low blood glucose - a "hypo") or hyperglycaemia (high blood glucose).

Low blood glucose can occur suddenly. Signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- tearfulness or crying
- irritability
- hunger
- numbness around the lips and tongue

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- loss of consciousness or seizures

Hypoglycaemia can be very dangerous so make sure that you and your family can recognize its symptoms and know how to react.

High blood glucose usually occurs more slowly than low blood glucose.

Signs of high blood glucose may include:

- lethargy or tiredness
- headache
- thirst
- passing large amounts of urine

- blurred vision

High blood glucose can lead to serious problems with your heart, eyes, circulation or kidneys.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is only available with a doctor's prescription.

There is no evidence that ARX-GLIMEPIRIDE is addictive.

Before you take ARX-GLIMEPIRIDE

When you must not take it

Do not take ARX-GLIMEPIRIDE if:

- **you have an allergy to:**
 - ARX-GLIMEPIRIDE tablets
 - Sulfonylureas
 - related medicines such as sulfur antibiotics or thiazide diuretics
 - any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to ARX-GLIMEPIRIDE may include skin rash, itchiness, shortness of breath, or difficulty breathing.

If you are not sure if you have an allergy to ARX-GLIMEPIRIDE tablets, check with your doctor.

- **you have previously had a reaction to glimepiride or any other sulfonylurea or sulfonamide**
- **you have or have had any of the following conditions:**
 - type 1 diabetes mellitus
 - unstable diabetes

- diabetic acidosis
- diabetic coma or pre-coma
- severe kidney disease or if you require dialysis
- severe liver failure glucose-6-phosphate dehydrogenase (G6PD) deficiency

If you are not sure if you have any of the above, ask your doctor.

- **you are pregnant or intend becoming pregnant**

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace ARX-GLIMEPIRIDE tablets with insulin.

- **you are breastfeeding or plan to breastfeed**

Glimepiride passes into breast milk and therefore there is the possibility that the breastfed baby may be affected.

- **the packaging is torn or shows signs of tampering (or the tablets do not look quite right)**

- **the expiry date printed on the pack has passed**

If you take this medicine after the expiry date has passed, it may not work as well.

Do not give ARX-GLIMEPIRIDE tablets to children.

There is not enough experience with the use of glimepiride in children.

If you are not sure whether you should start taking ARX-GLIMEPIRIDE, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

- **you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes**
- **you are breastfeeding or plan to breastfeed**
Glimepiride passes into breast milk and therefore there is the possibility that the breastfed baby may be affected.
- **you have or have had any of the following medical**

conditions

- kidney problems
- liver problems
- a history of diabetic coma
- adrenal, pituitary or thyroid problems
- heart failure
- glucose-6-phosphate dehydrogenase (G6PD) deficiency

- **you drink alcohol in any amount**

- **you do not eat regular meals**

- **you do a lot of exercise or you do heavy exercise or work**

- **you are ill or feeling unwell**
Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes.

- **you are taking any other anti-diabetic treatment**

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking ARX-GLIMEPIRIDE tablets.

Taking other medicines

Tell your doctor, pharmacist or diabetes educator if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood glucose-lowering effect of ARX-GLIMEPIRIDE. These include:

- alcohol
- other medicines used to treat diabetes
- anabolic steroids
- some antibiotics
- some antidepressants
- some medicines used to treat reflux and stomach ulcers.
- some anti-inflammatory agents, such as ibuprofen and naproxen
- some medicines used to treat arthritis and gout

- some blood pressure lowering medicines, such as beta-blockers and ACE inhibitors
- some medicines used to treat blood clots, blood vessel problems and irregular heart rhythms
- some cholesterol-lowering and weight reduction medicines
- some cancer and organ transplant treatments

Some medicines may lead to loss of control of your diabetes by weakening the blood glucose-lowering effect of ARX-GLIMEPIRIDE. These include:

- alcohol
- some antibiotics, such as rifampicin
- some blood pressure, cholesterol and heart medications
- some medicines used to treat reflux and stomach ulcers
- corticosteroids, glucagon, adrenaline and other hormonal therapies
- oral contraceptives
- some asthma medicines, preparations for coughs and colds, and weight reduction medicines
- some diuretic (fluid) and glaucoma treating medications
- large doses of laxatives
- some psychiatric and sedating medications
- some antiepileptics such as phenytoin
- some thyroid hormones

ARX-GLIMEPIRIDE tablets may change the effects of other medicines. These include:

- coumarin derivatives, which are used to prevent blood clots

Some medicines may hide the symptoms of low blood glucose (hypoglycaemia).

These include:

- alcohol
- certain heart medications, such as beta-blockers

You may need different amounts of your medicine or you may need to take different medicines. Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have a complete list of medicines to be careful with or avoid while taking ARX-GLIMEPIRIDE tablets.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to take ARX-GLIMEPIRIDE

Follow all directions given to you by your doctor, pharmacist or diabetes educator carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets to take each day.

Your doctor may increase or decrease the dose, depending on your blood glucose levels.

How to take it

Swallow ARX-GLIMEPIRIDE tablets whole with a glass of water.

When to take it

You must make sure that you take ARX-GLIMEPIRIDE tablets just before or with a meal.

ARX-GLIMEPIRIDE tablets are usually taken once a day, immediately before breakfast.

If you eat only a light breakfast, you should delay taking the tablet until after the first main meal of the day (eg lunch).

Do not skip meals while taking ARX-GLIMEPIRIDE.

How long to take it

Continue to take ARX-GLIMEPIRIDE for as long as your doctor recommends.

Make sure you keep enough ARX-GLIMEPIRIDE tablets to last over weekends and holidays.

ARX-GLIMEPIRIDE tablets will help control your diabetes but will not cure it. Therefore, you may have to take it for a long time.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Missed doses can cause high blood glucose (hyperglycaemia).

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed. If you double a dose, this may cause low blood glucose (hypoglycaemia).

If you take too much (Overdose)

Immediately telephone the Poisons Information Centre (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much ARX-GLIMEPIRIDE.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much ARX-GLIMEPIRIDE, you may experience the symptoms of low blood glucose (hypoglycaemia).

At the first signs of hypoglycaemia, raise your blood

glucose quickly by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- 1/2 can of a sugar-containing soft drink
- 2-3 concentrated glucose tablets

Unless you are within 10 to 15 minutes of your next meal, follow up with extra carbohydrates, e.g. plain biscuits, fruit or milk, when over the initial symptoms.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and seizures.

While you are taking ARX-GLIMEPIRIDE

Things you must do

If you become pregnant while taking ARX-GLIMEPIRIDE, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ARX-GLIMEPIRIDE.

Tell all doctors, dentists and pharmacists who are treating you that you are taking ARX-GLIMEPIRIDE.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking ARX-GLIMEPIRIDE.

Make sure all friends, relatives, workmates or carers know that you have diabetes. Make sure they can recognise the symptoms of hypoglycaemia and know how to treat them. Provide them with the telephone number for your doctor, the Poisons Information Centre (13 11 26) and Emergency Services.

Always carry some sugary food or drink with you.

If you experience any of the symptoms of low blood glucose (hypoglycaemia), immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Diet and low calorie soft drinks do NOT contain sugar and are unsuitable to take for hypoglycaemia.

If you are elderly or are taking other medicines for diabetes, the risk of hypoglycaemia is increased.

The risk of hypoglycaemia is also increased in the following situations:

- too much ARX-GLIMEPIRIDE
- too much or unexpected exercise
- delayed meal or snack
- too little food

If you experience any of the signs of high blood glucose (hyperglycaemia), contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- undiagnosed or uncontrolled diabetes
- illness, infection or stress
- too little ARX-GLIMEPIRIDE
- certain other medicines
- too little exercise
- sudden immobilisation, e.g. after an accident
- eating more carbohydrate than normal

If you become ill or experience extra stress, injury, fever, infection or need surgery, tell your doctor.

Your blood glucose may become difficult to control at these times.

Your doctor may decide to change your treatment and use insulin instead of ARX-GLIMEPIRIDE.

Make sure you check your blood glucose levels regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes

educator will show you how and when to do this.

Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

If you drink alcohol while taking ARX-GLIMEPIRIDE, you may get flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit.

Tell your doctor immediately if you notice the return of any symptoms you had before starting ARX-GLIMEPIRIDE.

These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision. These may be signs that ARX-GLIMEPIRIDE is no longer working, even though you may have been taking it successfully for some time.

Things you must not do

Do not give ARX-GLIMEPIRIDE tablets to anyone else, even if they have the same condition as you.

Do not skip meals while taking ARX-GLIMEPIRIDE.

Things to be careful of

Protect your skin when you are in the sun, especially between 10am and 3pm.

ARX-GLIMEPIRIDE may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn.

If outdoors, wear protective clothing and use a 15+ sunscreen. If your skin does appear to be burning, tell your doctor immediately.

If you have to be alert e.g. when driving, be especially careful not to let your blood glucose levels fall too low.

Low blood glucose levels may lower your reaction time and affect your ability to drive or operate machinery.

Drinking alcohol can make this worse. However, ARX-GLIMEPIRIDE by itself is unlikely to affect how you drive or operate machinery.

Make sure you know how you react to ARX-GLIMEPIRIDE before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, e.g. sugar sachets or jelly beans
- carry emergency food rations in case of a delay, e.g. dried fruit, biscuits or muesli bars
- keep ARX-GLIMEPIRIDE tablets readily available

If you become sick with a cold, fever or flu, it is very important to continue taking ARX-GLIMEPIRIDE, even if you feel unable to eat your normal meal. If you have trouble eating solid foods, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food. Your diabetes educator or dietician can give you a list of food to use for sick days.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARX-GLIMEPIRIDE.

ARX-GLIMEPIRIDE helps most people with diabetes, but it may

have unwanted side effects in a few people

All medicines can have side effects.

Sometimes they are serious, most of the time they are not.

You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- signs of hypoglycaemia, which may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers
- eye problems, including blurred or double vision
- stomach upset including nausea (feeling sick) and vomiting
- diarrhoea, abdominal pain or a feeling of fullness in the stomach

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- rash, sores, redness or itching of the skin, itchy hives-like rash or spots
- symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal
- bleeding or bruising more easily than normal, or reddish or purplish blotches under the skin
- yellowing of the skin or eyes, also called jaundice
- signs of frequent or worrying infections, such as fever, severe chills, sore throat or mouth ulcers
- signs of anaemia, such as tiredness, being short of breath and looking pale.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them

After taking ARX-GLIMEPIRIDE

Storage

Keep all medicines out of reach of children.

Keep ARX-GLIMEPIRIDE tablets in a cool, dry place where it stays below 25°C.

Keep ARX-GLIMEPIRIDE tablets in its original pack until time to take them.

Do not take ARX-GLIMEPIRIDE tablets after the expiry date.

Return any unused or expired medicine to your pharmacist.

Disposal

If your doctor tells you to stop taking ARX-GLIMEPIRIDE or the expiry date has passed, ask your pharmacist what to do with any medicine that you have left over.

Product description

What ARX-GLIMEPIRIDE looks like

ARX-GLIMEPIRIDE 1 mg:
(AUST R 281224)

Pink round flat uncoated tablets with breakline on one side and plain on the other side of the tablet.

ARX-GLIMEPIRIDE 2 mg:
(AUST R 281225)

Light pink oval shaped uncoated tablets with score line on one side and plain on the other side of the tablet.

ARX-GLIMEPIRIDE 3 mg:
(AUST R 281226)

Pale yellow oval shaped uncoated tablets with breakline on one side and plain on the other side of the tablet.

ARX-GLIMEPIRIDE 4 mg:
(AUST R 281227)

White coloured oval shaped uncoated tablets with scoreline on one side and plain on the other side of the tablet.

The tablets are packed in blister packs of 10 tablets (1mg, 2mg) and 30 tablets (1mg, 2mg, 3mg, 4mg).

Ingredients

Active ingredient

Glimepiride

Inactive ingredients

- lactose
- sodium starch glycollate
- povidone
- magnesium stearate

In order to distinguish between the different tablet strengths, each strength contains different colourings. These are:

- iron oxide red (1 mg)
- iron oxide yellow and indigo carmine aluminium lake (2 mg)
- iron oxide yellow (3 mg)
- indigo carmine aluminium lake (4 mg)

Name and Address of the Sponsor

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