

Vexazone

contains the active ingredient pioglitazone hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Vexazone.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Vexazone against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Vexazone is used for

Vexazone is used to treat type 2 diabetes mellitus not adequately controlled by diet and exercise.

Type 2 diabetes is also known as non-insulin dependent diabetes mellitus or adult-onset diabetes, and is controlled by diet, exercise, certain oral medications and occasionally insulin.

Vexazone is a member of a class of drugs that are insulin-sensitising agents. These medicines help control the level of sugar in your blood when you have type 2 diabetes by helping your body make better use of the insulin it produces.

Vexazone may be used on its own (when diet and exercise is not enough to treat your diabetes) or in combination with metformin and/or a

sulphonylurea which are also oral anti-diabetic medicines.

It may also be used in combination with insulin.

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

Your doctor may have prescribed it for another reason.

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

The use of Vexazone has not been studied in children.

Before you take Vexazone

When you must not take it

Do not take Vexazone if:

- you have heart failure requiring treatment. Talk to your doctor if you have heart failure
- type 1 diabetes or diabetic ketoacidosis (often caused by very high blood glucose levels)
- you have an allergy to any medicine containing pioglitazone hydrochloride or any of the ingredients listed at the end of this leaflet (see 'Product Description')

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Vexazone if you have heart failure requiring treatment.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

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Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease with shortness of breath after minimal physical activity
- heart disease with severe symptoms at rest
- swelling of hands, ankles or feet
- liver problems
- kidney problems that require dialysis. Vexazone is not recommended for use if you are on dialysis

Talk to your doctor about the risk of fracture and for advice on how to keep your bones healthy.

Fractures, usually in the hand, upper arm or foot, have been seen in some women when taking Vexazone.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breastfeed.

It is not known whether Vexazone passes into breast milk. Therefore, it is recommended to not breast-feed while taking this medicine.

Talk to your doctor if you are a woman who has not reached menopause, but have no menstrual periods.

You may become pregnant unless you use an effective method of birth control. Vexazone, like other drugs in this class, may cause women with insulin resistance to ovulate again.

Tell your doctor if you are using another medicine for diabetes.

Vexazone can enhance the action of other medicines. You may be at risk of low blood sugar (hypoglycaemia). If this happens, your doctor may need to adjust the dose of your other medicines.

Tell your doctor if you suffer from lactose intolerance.

Vexazone tablets contain lactose.

If you have not told your doctor about any of the above, tell him/her before you start taking Vexazone.

Taking other medicines

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

Some medicines and Vexazone may interfere with each other. These include:

- chlorpropamide
- glibenclamide
- gliclazide
- insulin
- metformin
- oral contraceptives
- gemfibrozil
- rifampicin
- tolbutamide

These medicines may be affected by Vexazone or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist have more information on medicines to be careful with or to avoid while taking this medicine.

How to take Vexazone

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

The dose varies from person to person. Your doctor will decide the right dose for you.

The usual dose is 15 mg or 30 mg once daily, increasing after four weeks to 45 mg once daily if needed.

Do not exceed 45 mg once daily.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Vexazone must be taken once daily, at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

This medicine helps to control your condition, but does not cure it. It is

important to keep taking your medicine even if you feel well.

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 your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Vexazone. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Vexazone

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Vexazone.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you have gained weight since taking this medicine.

Weight gain can be associated with improved blood sugar control; however, it may also be a symptom of heart failure.

Things you must not do

Do not take Vexazone to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Vexazone alone is unlikely to affect your ability to drive or operate machinery. However, be careful not to let your blood glucose levels fall too low whilst driving or operating machinery if using Vexazone in combination with other anti-diabetic medicines.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

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

This medicine helps most people with type 2 diabetes not controlled by diet, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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 (low blood sugar), which may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat
- a small increase in weight
- headache
- back pain
- joint pain
- aching muscles, muscle tenderness or weakness, not caused by exercise
- generally feeling unwell
- abnormal vision.

Tell your doctor as soon as possible if you notice any of the following:

- weight gain. Tell your doctor if you gain a lot of weight in a short period of time.
- oedema (fluid retention or swelling of the hands, ankles or feet) which could lead to heart failure
- fractures in women.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- blurred or decreased vision, which may be due to swelling (or fluid) in the back of the eye

- dark urine or pale stools, yellowing of the skin or eyes, severe cramps of the stomach, nausea or vomiting, loss of weight, tiredness
- heart failure or fluid in the lungs (pulmonary oedema): trouble breathing or shortness of breath, getting tired easily after light physical activity, unusual tiredness, waking up short of breath at night, swollen ankles or feet, unusually rapid increase in weight
- signs of an allergic reaction such as skin rash, itching or hives; shortness of breath, wheezing or trouble breathing; swelling of the face, lips, tongue or other parts of the body.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

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

After taking Vexazone

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C, protect from light.

Do not store Vexazone or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

Vexazone tablets come in 4 strengths:

- Vexazone 15 mg - white to off-white, round, bi-convex, uncoated tablet debossed with "PG" over 15 on one side and "G" on the other side
- Vexazone 30 mg - white to off-white, round, bi-convex, uncoated tablet debossed with "PG" over 30 on one side and "G" on the other side
- Vexazone 45 mg - white to off-white, round, bi-convex, uncoated tablet debossed with "PG" over 45 on one side and "G" on the other side.

Each blister pack contains 28 tablets.

Ingredients

The active ingredient in Vexazone is pioglitazone:

- each Vexazone 15 tablet contains 15 mg of pioglitazone
- each Vexazone 30 tablet contains 30 mg of pioglitazone
- each Vexazone 45 tablet contains 45 mg of pioglitazone

The tablets also contain the following inactive ingredients:

- lactose
- hypromellose
- silica - colloidal anhydrous
- croscarmellose sodium
- polysorbate 80
- magnesium stearate.

The tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Vexazone is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

ABN 93 002 359 739

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration number:

Vexazone 15mg AUST R 164345

Vexazone 30mg AUST R 164344

Vexazone 45mg AUST R 164343

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