

VEXAZONE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking VEXAZONE?

VEXAZONE contains the active ingredient pioglitazone hydrochloride. VEXAZONE is used in the management of type 2 diabetes not controlled by diet.

For more information, see Section [1. Why am I taking VEXAZONE?](#) in the full CMI.

2. What should I know before I take VEXAZONE?

Do not use if you have ever had an allergic reaction to VEXAZONE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take VEXAZONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VEXAZONE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take VEXAZONE?

- VEXAZONE should be taken at the same time every day to ensure it works effectively.
- Follow all instructions given to you by your doctor.

More instructions can be found in Section [4. How do I take VEXAZONE?](#) in the full CMI.

5. What should I know while taking VEXAZONE?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking VEXAZONE.• Monitor your health and contact your doctor if you notice any changes.

	<ul style="list-style-type: none"> • Keep all of your doctor's appointments and go for regular check-ups.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none"> • VEXAZONE may cause dizziness in some people. Do not drive or operate machines until you know how this medicine affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Store VEXAZONE in a cool dry place, out of direct light, where the temperature is below 25°C. • Keep VEXAZONE in the original packaging, in a safe place, away from children.

For more information, see Section [5. What should I know while taking VEXAZONE?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include weight gain, signs of low blood sugar (hypoglycaemia), eye problems, bone fracture and impaired liver function. Serious side effects may include dark urine, pale stools, yellowing skin or eyes, severe stomach cramps, nausea or vomiting, weight loss, tiredness, shortness of breath with swelling of legs, feet and hands, with rapid increase in weight, signs of bladder cancer, and oedema (signs of heart failure).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

VEXAZONE®

Active ingredient(s): *pioglitazone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking VEXAZONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking VEXAZONE.**

Where to find information in this leaflet:

1. Why am I taking VEXAZONE?
- [2. What should I know before I take VEXAZONE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take VEXAZONE?](#)
- [5. What should I know while taking VEXAZONE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

Why am I taking VEXAZONE?

VEXAZONE contains the active ingredient pioglitazone hydrochloride. VEXAZONE belongs to a group of medicines called glitazones. Glitazones decrease insulin resistance.

VEXAZONE is used in the management of type 2 diabetes not controlled by diet.

VEXAZONE is a tablet that is used to improve the action of the body's naturally produced insulin. VEXAZONE helps to control the level of glucose in your blood when you have type 2 diabetes. This is the 'adult onset' type of diabetes and is controlled by diet, certain oral medications and occasionally insulin. VEXAZONE can be used alone (when diet and exercise is not enough to treat your diabetes) or together with other anti-diabetic medicines.

Your doctor may have prescribed it for another purpose.

7. What should I know before I take VEXAZONE?

Warnings

Do not take VEXAZONE if:

- you are allergic to pioglitazone hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
 - 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.
- you have heart failure requiring treatment. Talk to your doctor if you have heart failure.
- you have type 1 diabetes or diabetic ketoacidosis (often caused by very high blood glucose levels).

Check with your doctor if you:

- heart disease with shortness of breath after minimal physical activity
- heart disease with severe symptoms at rest
- swelling of hands, ankles or feet
- bladder cancer or symptoms associated with bladder cancer such as blood in the urine (hematuria) often accompanied by pain and burning
- problems with your liver
- problems with your kidneys that require dialysis. VEXAZONE is not recommended for use if you are on dialysis
- some women who do not have monthly periods and have not been through menopause may restart their periods when taking VEXAZONE. These women may be at increased risk of pregnancy.
- bone fractures, usually in the hand, upper arm or foot, have been seen in some women when taking VEXAZONE. Talk to your doctor about the risk of fracture and for advice on how to keep your bones healthy.
- allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

VEXAZONE is not recommended for use during pregnancy. If there is a need to consider VEXAZONE during your pregnancy, your doctor will discuss with you the benefits and risks of taking VEXAZONE.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is recommended you do not breastfeed while taking VEXAZONE and it is not known whether VEXAZONE passes into breast milk.

Use in children

The use of VEXAZONE has not been studied in children.

8. What if I am taking other medicines?

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

Some medicines may interfere with VEXAZONE and affect how it works. These include:

- chlorpropamide
- glibenclamide
- gliclazide

- insulin
- metformin
- oral contraceptives
- gemfibrozil
- rifampicin
- tolbutamide

If you are taking any of these medicines you may need to adjust your dose or take different medicines. Your doctor will be able to provide information.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VEXAZONE.

9. How do I take VEXAZONE?

How much to take

- Your doctor will tell you how many VEXAZONE tablets you should take.
- The dose your doctor will prescribe for you will usually be in the range of 15 mg to 45 mg per day.
- Your doctor may increase or decrease your dose in order to find the appropriate dose for your condition.
- Follow the instructions provided by your doctor as they might be different to the information in this leaflet.

When to take VEXAZONE

- Take VEXAZONE once a day the same time each day as advised by your doctor.

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

How to take VEXAZONE

- VEXAZONE tablets should be swallowed whole with a glass of water.
- VEXAZONE tablets can be taken before or after food.

How long to take VEXAZONE for

- Continue taking your medicine until your doctor tells you to stop.
- 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 VEXAZONE

VEXAZONE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you are not sure what to do, ask your pharmacist for help. Your pharmacist can also provide some hints if you have trouble remembering.

If you take too much VEXAZONE

If you think that you have used too much VEXAZONE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

10. What should I know while taking VEXAZONE?

Things you should do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. VEXAZONE may affect other medicines used during surgery.

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.

Call your doctor straight away if you:

- become pregnant while taking this medicine

Things you should not do

- 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.
- 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.

Hypoglycaemia (low blood sugar)

- If you are taking VEXAZONE with other medications used to treat diabetes such as a sulfonylurea or insulin you may be at risk for hypoglycaemia.
- Signs of hypoglycaemia (low blood sugar), which may include sweating, weakness, hunger, dizziness, trembling or shaking, light-headedness, headache,

lack of concentration, tearfulness or crying, irritability, numbness around the lips and fingers.

You should tell your doctor as soon as possible if you notice the above side effects.

Heart failure

- If you are taking VEXAZONE in combination with insulin you may be at risk of heart failure which may show as localised swelling of the ankles, feet and hands (oedema) and/or fluid in the lungs (pulmonary oedema).
- Tell your doctor if you have gained weight since taking VEXAZONE. Weight gain can be associated with improved blood sugar control; however, it may also be a symptom of heart failure.

You should tell your doctor as soon as possible if you notice the above side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VEXAZONE affects you.

If your blood glucose level becomes too low, you may feel dizzy, light headed, weak or tired and your reaction time may be slower than usual.

If you experience any side effects which impact your ability to drive or operate machinery when taking this medicine, do not drive or do anything else that could be dangerous and contact your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

11. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Some side effects may be related to the dose of VEXAZONE. Accordingly, it is important that you tell your doctor as soon as possible about any unwanted effects. Your doctor may then decide to adjust the dose of VEXAZONE you are taking.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • weight gain • signs of hypoglycaemia (low blood sugar), which may include sweating, weakness, hunger, dizziness, trembling or shaking, light-headedness, headache, lack of concentration, tearfulness or crying, irritability, numbness around the lips and fingers • eye problems including blurred or double vision. • increased risk of fracture in women • macular oedema (an eye disorder that can affect vision) 	<p>Speak to your doctor if you have any of these less serious side effects.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • altered or impaired liver function. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • dark urine or pale stools, yellowing of the skin or eyes, severe cramps of the stomach, nausea or vomiting, loss of weight, tiredness • blood in the urine often accompanied by pain and burning, these can be symptoms of bladder cancer. • shortness of breath when at rest or after minimal physical activity with swelling of the legs, feet and hands, rapid increase in weight • heart failure which may show as localised swelling of the ankles, feet and hands (oedema) and/or fluid 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
in the lungs (pulmonary oedema).	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

12. Product details

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

What VEXAZONE contains

Active ingredient (main ingredient)	pioglitazone (as hydrochloride)
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • hypromellose • colloidal anhydrous silica • croscarmellose sodium • polysorbate 80 • magnesium stearate
Potential allergens	Contains sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What VEXAZONE looks like

VEXAZONE tablets come in 3 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 (AUST R 164345)
- 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 (AUST R 164344)
- 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. (AUST R 164343).

Who distributes VEXAZONE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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VEXAZONE® is a Viatris company trade mark

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