ACARBOSE VIATRIS

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ACARBOSE VIATRIS?

ACARBOSE VIATRIS contains the active ingredient acarbose. ACARBOSE VIATRIS is used for the treatment of diabetes. For more information, see Section <u>1. Why am I using ACARBOSE VIATRIS?</u> in the full CMI.

2. What should I know before I use ACARBOSE VIATRIS?

Do not use if you have ever had an allergic reaction to acarbose 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 use ACARBOSE VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ACARBOSE VIATRIS 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 use ACARBOSE VIATRIS?

- Follow all directions given to you by your doctor or pharmacist carefully.
- Swallow the tablets whole with a little liquid immediately before the meal. If you prefer not to swallow the tablets then chew the tablets with the first few mouthfuls of food.
- Take your medicine at about the same time each day with breakfast, lunch and dinner.

More instructions can be found in Section 4. How do I use ACARBOSE VIATRIS? in the full CMI.

5. What should I know while using ACARBOSE VIATRIS?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using ACARBOSE VIATRIS. Take ACARBOSE VIATRIS exactly as instructed by your doctor. If you do not follow your doctor's instructions, your blood sugar level may not be controlled.
Things you should not do	 Do not take ACARBOSE VIATRIS 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.
Looking after your medicine	 Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from moisture. Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

For more information, see Section 5. What should I know while using ACARBOSE VIATRIS? in the full CMI.

6. Are there any side effects?

Common side effects includes: flatulence (wind), abdominal 'rumbling' noises, a feeling of fullness, softer stools or have diarrhoea; particularly if you have eaten foods containing sugar; stomach cramps, nausea, indigestion, vomiting, increased appetite, dizziness, loss of appetite. Serious side effects include: jaundice (yellowing of the skin), swelling from fluid retention, inflammation of the liver (hepatitis), intestinal obstruction, decrease in platelet count, skin reactions such as redness, rash and urticaria (hives).

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.

ACARBOSE VIATRIS

Active ingredient(s): acarbose

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- 1. Why am I using ACARBOSE VIATRIS?
- 2. What should I know before I use ACARBOSE VIATRIS?
- 3. What if I am taking other medicines?
- 4. How do I use ACARBOSE VIATRIS?
- 5. What should I know while using ACARBOSE VIATRIS?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

1. Why am I using ACARBOSE VIATRIS?

ACARBOSE VIATRIS contains the active ingredient acarbose.

ACARBOSE VIATRIS is used for the treatment of diabetes.

Acarbose helps to control your blood sugar levels in conjunction with diet, exercise, weight loss and other measures by slowing down the digestion of carbohydrates (complex sugars) from your diet. This reduces the abnormally high blood sugar levels that occur after each meal.

2. What should I know before I use ACARBOSE VIATRIS?

Warnings

Do not use ACARBOSE VIATRIS if:

- you are allergic to acarbose, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- you have a severe kidney disorder (creatinine clearance <25 mL/min).
- you suffer from intestinal obstruction, inflammation or ulceration of the bowel, e.g. ulcerative colitis or Crohn's disease.
- you have a hernia or have had previous abdominal surgery. If so, consult your doctor first.

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

Do not take this medicine if the packaging is torn or shows signs of tampering. If the packaging is damaged, return it to your pharmacist for disposal.

Do not give this medicine to a child under the age of 18 years.

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

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

Like most medicines of this kind, acarbose is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether acarbose passes into breast milk.

3. 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 ACARBOSE VIATRIS and affect how it works. These include:

- Neomycin (Neosulf[™])
- Colestyramine (Questran Lite[™])
- Intestinal adsorbents (e.g. charcoal)
- Digestive enzyme preparations (Cotazym-S Forte[™], Creon[™], Pancrease[™], Viokase[™])
- Digoxin

([™] indicates trademark of the original manufacturer/supplier)

These medicines may be affected by ACARBOSE VIATRIS 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

You should avoid taking cane sugar (sucrose) and products containing sugar. They may cause stomach discomfort or even diarrhoea if taken while you are on ACARBOSE VIATRIS tablets.

If you are taking other medicines containing sulfonylureas or metformin or tend to have low blood sugar levels, tell your doctor before using ACARBOSE VIATRIS. If you have not told your doctor or pharmacist about any of the above, tell them before you start taking ACARBOSE VIATRIS.

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

4. How do I use ACARBOSE VIATRIS?

How much to take

To gain the maximum benefit from ACARBOSE VIATRIS it is important that you follow the prescribed diet as well as taking the exact dose prescribed by your doctor. This will help control your blood sugar levels and reduce side effects experienced.

At the start of treatment, your doctor may prescribe a low dose of ACARBOSE VIATRIS. Your doctor will determine the correct dose for you depending on your condition, other medicines and your response to the treatment. The average adult dose is one ACARBOSE VIATRIS 100 mg tablet taken three times daily.

Swallow the tablets whole with a little liquid immediately before the meal. If you prefer not to swallow the tablets then chew the tablets with the first few mouthfuls of food.

When to take ACARBOSE VIATRIS

- Take ACARBOSE VIATRIS at about the same time each day with breakfast, lunch and dinner. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- When you first start your treatment, your doctor may recommend that you take your tablets once or twice a day, before increasing your dose to three times a day.

Follow the instructions provided and use ACARBOSE VIATRIS until your doctor tells you to stop.

If you forget to use ACARBOSE VIATRIS

If you forget to take ACARBOSE VIATRIS at the time you are supposed to, do not take the tablets between meals. Wait until it is time for you to take your next dose and take ACARBOSE VIATRIS with your meal and continue as before. Do not take a double dose.

If you use too much ACARBOSE VIATRIS

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

You should immediately:

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

When ACARBOSE VIATRIS is taken with drinks and/or meals containing carbohydrates, overdosage can lead to diarrhoea and other intestinal symptoms such as flatulence (wind) and abdominal cramps. You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ACARBOSE VIATRIS?

Things you should do

Take ACARBOSE VIATRIS exactly as instructed by your doctor. If you do not follow your doctor's instructions, your blood sugar level may not be controlled.

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

Remind any doctor, dentist or pharmacist you visit that you are using ACARBOSE VIATRIS.

What to be careful of

Treating hypoglycaemia: ("hypos" or low blood sugar).

As a diabetic you may also be receiving other medicines for your diabetes. If ACARBOSE VIATRIS is prescribed for you in addition to sulfonylureas, metformin or insulin to control your diabetes, your doctor may need to adjust the dosages of these drugs to avoid the occurrence of "hypos" (low blood sugar levels).

When taking ACARBOSE VIATRIS together with these drugs, do not treat a "hypo" with ordinary sugar (sucrose). It will not work fast enough. Instead, you should take some GLUCOSE (also known as dextrose) tablets, honey, syrup or sweets which should be available from your local chemist.

After taking ACARBOSE VIATRIS

When treatment with ACARBOSE VIATRIS is to be stopped, your prescribing doctor may need to alter the dose of other medication(s) accordingly and monitor your condition.

Things you should not do

- Do not take ACARBOSE VIATRIS 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. 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.

Looking after your medicine

- 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 moisture.

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

Store it in a cool dry place 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 use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

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.

These side effects are more common at the start of the treatment, but some may persist or develop after treatment, or when dosage of acarbose is adjusted by your doctor.

Less serious side effects

Less serious side effects	What to do
 flatulence (wind) abdominal 'rumbling' noises a feeling of fullness softer stools or have diarrhoea; particularly if you have eaten foods containing sugar. stomach cramps nausea indigestion vomiting increased appetite dizziness loss of appetite 	Speak to your doctor if you have any of these less serious side effects and they worry you.

These symptoms may get worse if you do not keep to your prescribed diet. If your symptoms persist for more than 2 or 3 days, or if they are severe, consult your doctor or nearest emergency department particularly in the case of diarrhoea. Do not take antacids to treat these symptoms as they are unlikely to give you any relief.

Serious side effects

Serious side effects	What to do
 jaundice (yellowing of the skin) swelling from fluid retention inflammation of the liver (hepatitis) intestinal obstruction 	Call your doctor straight away, or go straight to the Emergency Department at

Serious side effects	What to do
 decrease in platelet count skin reactions such as redness, rash and urticaria (hives) 	your nearest hospital if you notice any of these serious side effects.

If while undergoing treatment with acarbose, you experience any side-effects or symptoms which you think may be due to this medication (whether or not it is mentioned in this leaflet) please inform your doctor or pharmacist as early as possible. You may need medical treatment in some cases.

ACARBOSE VIATRIS tablets may cause an increase in the results of certain liver function tests. Therefore, your doctor may conduct blood tests to monitor your liver function during the first 6 to 12 months of treatment with ACARBOSE VIATRIS.

These effects go away when treatment is stopped.

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 <u>www.tga.gov.au/reporting-problems</u>. 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.

7. Product details

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

What ACARBOSE VIATRIS contains

Active ingredient (main ingredient)	acarbose
Other ingredients (inactive ingredients)	 colloidal anhydrous silica magnesium stearate microcrystalline cellulose pregelatinised maize starch
Potential allergens	

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

What ACARBOSE VIATRIS looks like

ACARBOSE VIATRIS are available in blister pack of 90s in two strengths.

ACARBOSE VIATRIS 50 mg tablets are round, biconvex, white to off-white, marked with "ACA 50" on one side. (Aust R 226796).

ACARBOSE VIATRIS 100 mg tablets are round, biconvex, white to off-white, marked with a score line on one side, and "ACA 100" on the reverse side. (Aust R 226797).

Who distributes ACARBOSE VIATRIS

Arrotex Pharmaceuticals Pty Ltd 15-17 Chapel Street Cremorne VIC 3121 Australia www.arrotex.com.au

This leaflet was prepared in September 2024.