ACARBOSE VIATRIS

Consumer Medicine Information (CMI) summary

The full CMI 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 1. Why am I using ACARBOSE VIATRIS? 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?

- 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 VIATRS 100 mg tablet taken three times daily.

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. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking acarbose. Take ACARBOSE VIATRIS exactly as instructed by your doctor.
Things you should not do	 Do not stop using this medicine suddenly or lower the dosage without checking with your doctor. 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.
Looking after your medicine	 Keep your tablets in a cool dry place below 25°C. Protect from moisture. Keep it where children cannot reach it.

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

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: flatulence (wind), abdominal "rumbling" noises, a feeling of fullness, softer stools or have diarrhoea; particularly if you have eaten foods containing sugar.

Tell your doctor immediately if you notice 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).

Tell your doctor immediately if you notice any of the following side effects: 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. They may be the signs of an allergic reaction.

ACARBOSE VIATRIS tablets may cause an increase in the results of certain liver function tests.

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: 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?
- 6. Are there any side effects?
- 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.
- 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.
- Always check the ingredients to make sure you can use this medicine.
- 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.
- Do not give this medicine to a child under the age of 18 years.
- Do not take this medicine if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition.

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.

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.

- 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.

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.

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

When to take ACARBOSE VIATRIS

- ACARBOSE VIATRIS should be used 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.

How to take ACARBOSE VIATRIS

- 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.

How long to take ACARBOSE VIATRIS

- Do not stop taking the tablets unless you are told to do so by your doctor.
- 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.
- When treatment with ACARBOSE VIATRIS is to be stopped, your doctor may need to alter the dose of other medication(s) accordingly and monitor your condition.

If you forget to use ACARBOSE VIATRIS

ACARBOSE VIATRIS should be used regularly about at the same time each day.

If you miss your dose at the usual time, 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 to make up for the dose you missed.

If you use too much ACARBOSE VIATRIS

If you think that you have used too much ACARBOSE VIATRIS, avoid foods or drinks containing carbohydrates.

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 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.

You may need urgent medical attention.

5. What should I know while using ACARBOSE VIATRIS?

Things you should do

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

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.

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

Things you should not do

- Do not stop using this medicine suddenly 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 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.

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.

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.

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

Store it in a cool dry place where the temperature stays 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. A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

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?

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.

The 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.

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

More common side effects

More common 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 	Speak to your doctor if you have any of these side effects and they worry you.

Normally these symptoms will disappear if you continue treatment and keep to your prescribed diet. 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.

Less common side effects

Less common side effects	What to do
 stomach cramps nausea indigestion vomiting increased appetite dizziness loss of appetite 	Speak to your doctor if you have any of these side effects and they worry you.

Rare side effects

Rare side effects	What to do
 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) 	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.

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

You may need medical treatment in some cases.

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

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.

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.

7. Product details

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

What ACARBOSE VIATRIS contains

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

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

What ACARBOSE VIATRIS looks like

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

Sponsor

Generic Partners Pty Ltd

313 Burwood Road

Hawthorn VIC 3122

Australia

Distributor

ACARBOSE VIATRIS is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

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