

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ACCARB

Acarbose Tablets 50 mg & 100 mg



What is in this leaflet

Please read this leaflet carefully before you start taking ACCARB.

This leaflet answers some common questions about ACCARB.

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 ACCARB against the benefits they expect it will 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 ACCARB is used for

ACCARB is used to treat diabetes (both type 1, insulin-dependent diabetes and type 2, non-insulin-dependent diabetes) in association with diet.

ACCARB tablets contain the active ingredient acarbose. It 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.

Your doctor may have prescribed it for another reason.

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

you.

ACCARB is not known to be addictive.

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

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take ACCARB

When you must not take it:

Do not take ACCARB if you have an allergy to:

- any medicine containing acarbose
- 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.

Do not take this medicine if you have:

- severe kidney or liver problems
- inflammatory bowel disorders
- long-term bowel disorders associated with digestion and absorption problems
- a condition that may be worsened by increased gas formation in the bowel such as larger hernias (indicated by belchem or heart burn), intestinal obstructions or intestinal ulcers, ulcerative colitis (indicated by

diarrhoea, usually with blood and mucus, stomach pain and fever) or Crohn's disease (indicated by pain, fever, diarrhoea and loss of weight).

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in ACCARB might pass into breast milk and there is a possibility that your baby may be affected.

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.

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:

- kidney problems
- liver problems
- bowel, digestion or absorption problems.

If you have not told your doctor about any of the above, tell them before you start taking ACCARB.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines

that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking ACCARB.

Some medicines may interfere with ACCARB. These include:

- digoxin, a medicine to treat chronic heart failure or irregular heart rhythms
- oral neomycin antibiotic
- cholestyramine, a medicine used to help reduce cholesterol, relieve itching due to bile, or relieve some causes of diarrhoea
- intestinal adsorbents such as charcoal
- digestive enzyme preparations containing carbohydrate splitting enzymes (e.g. amylase or pancreatin) such as Panzytrat™, Creon™.

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

If you are using other medicines for diabetes, such as insulin, metformin or sulfonylureas and tend to have low blood sugar levels, tell your doctor before using ACCARB.

You should avoid taking cane sugar (sucrose) and products containing cane sugar.

They may cause abdominal discomfort or even diarrhoea if taken while you are on ACCARB tablets.

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

How to take ACCARB

Follow all directions given to you by your doctor or 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

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

When and How to take it

Take the tablets as prescribed by your doctor. This will normally be one or two tablets taken with breakfast, lunch and dinner.

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

The average adult dose is one ACCARB 100 mg tablet taken with breakfast, lunch and dinner.

Take your medicine at about the same times each day with breakfast, lunch and dinner.

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

How long to take it

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

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 you forget to take ACCARB 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 ACCARB with your meal and continue as before.

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

missed.

This may increase the chance of you getting an unwanted side effect.

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.

While you are taking ACCARB

Things you must do

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

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. It may affect other medicines used during surgery.

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 (such as blood tests to check your blood sugar levels and liver function) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take ACCARB 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 change the dosage without checking with your doctor.

Things to be careful of

Treating hypoglycaemia (“hypos” or low blood sugar):

You may also be receiving other medicines for your diabetes. If ACCARB is prescribed for you in addition to sulfonylureas, insulin or metformin to control your diabetes, your doctor may need to adjust the dosages of your medicines to avoid the occurrence of “hypos”. When taking ACCARB together with these medicines, do not treat a “hypo” with cane sugar (sucrose). It will not work fast enough. Instead, you should take some GLUCOSE (also known as dextrose) or honey. Glucose is available in tablets, syrup or sweets, which should be available from your local pharmacy.

Be careful driving or operating machinery until you know how ACCARB affects you.

When used with some other medicines for diabetes, “hypos” or low blood sugar or dizziness may occur in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In case of overdose

If you take too much (overdose)

Avoid food or drinks containing carbohydrates and immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at the nearest hospital, if you think that you or anyone else may have taken too much ACCARB. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

When ACCARB 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.

Side effects

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

This medicine helps most people with diabetes, but it may have unwanted side effects in few 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.

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

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

- increased flatulence (wind)
- abdominal pain or discomfort
- diarrhoea.

The above list includes some of the more common side effects of your medicine. Often these symptoms will disappear if you continue treatment and keep to your prescribed diet. If you eat or drink products containing cane sugar (sucrose), these side effects could get worse.

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

- nausea
- vomiting
- indigestion
- more easily bleeding or bruising than normal
- loss of appetite
- formation of pus containing blisters.

The above list includes some of the less common side effects.

If you are concerned, or any of your symptoms are severe, talk to your doctor as soon as possible.

When ACCARB is taken together with other medicines for diabetes, such as sulfonylureas, insulin or metformin, hypoglycemia (“hypos” or low blood sugar levels) can occur. Symptoms of hypoglycemia may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, a fast, pounding heartbeat. Let your doctor know if you notice any of the above, as your doctor may need to adjust the dosages of your medicines.

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

- jaundice (yellowing of the skin or eyes)
- severe stomach or abdominal pain
- skin rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or troubled breathing
- fever
- dark coloured urine.

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 occur in some people. Tell your doctor if you notice any other effects.

Some side effects, for example, changes in numbers of blood cells, inflammation of the liver (hepatitis), changes in liver enzyme levels, can only be found when your doctor does tests from time to time to check your progress.

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

After taking ACCARB

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.

Do not store ACCARB or any other medicine in the bathroom or near a sink. Do not leave it on a window sill 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

ACCARB tablets are available in blister packs of 90 tablets in two strengths.

ACCARB 50 mg tablets: White to off-white round tablet, embossed with 'AA' breakline '50' on one side and 'G' on the reverse, approximately 7 mm in diameter.

ACCARB 100 mg tablets: White to off-white oval shaped tablet, embossed with 'AA' breakline '100' on one side and 'G' scoreline on the reverse, approximately 13 mm x 6.5 mm.

Ingredients

Active ingredient(s):

ACCARB 50 contains 50 mg of acarbose as the active ingredient.

ACCARB 100 contains 100 mg of acarbose as the active ingredient.

Inactive ingredient(s):

ACCARB tablets also contain:

- Microcrystalline Cellulose (PH102)
- Dried Maize Starch
- Colloidal Anhydrous Silica
- Magnesium Stearate.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any azo dyes.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

ACCARB is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Eilerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

26 February 2019
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