APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

CARBUCE 500 (Film-coated tablets)

CARBUCE 850 (Film-coated tablets)

CARBUCE 1000 (Film-coated tablets)

Metformin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking CARBUCE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CARBUCE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CARBUCE is and what it is used for

CARBUCE belongs to a class of medicines called oral hypoglycaemics. It is indicated for the treatment of type 2 diabetes mellitus.

Patients with type 2 diabetes mellitus have too much glucose in their blood; either because their pancreas produces too little insulin or because the cells in theirbody are insulin resistant (not sensitive to insulin). Insulin is an important hormone that enables your body to take glucose from the blood and to use it as energy or to store it for future use. Metformin, the active ingredient in CARBUCE, helps to bring your blood glucose levels down by making your cells more sensitive to insulin and also possibly by delaying absorption of glucose from your gut and by decreasing your liver's production of glucose. CARBUCE can be used by adults with type 2 diabetes mellitus as single agent to control their disease, or in combination with other medicines or injectable insulin. Children older than 12 years and teenagers with type 2 diabetes may also use CARBUCE as single agent or in combination with insulin.

2. What you need to know before you take CARBUCE

Do not take CARBUCE:

- if you are allergic (hypersensitive) to metformin or any of the other ingredients of CARBUCE (listed in section 6),
- if you have renal failure or abnormal renal function. Please discuss with your doctor if you are unsure,
- if you suffer from serious complications from your diabetes previously, especially if you had a condition known as diabetic ketoacidosis. Please discuss with your doctor if you are unsure,
- If you suffer from any of the following conditions:

- Dehydration.
- Severe infection.
- Shock (poor blood circulation with very low blood pressure).
- Heart or liver failure.

- Recent heart attack.
- Any disease of your pancreas.
- Liver disease.
- Alcoholism, or if you are a heavy drinker of alcohol.

- if you are scheduled for x-ray, CT-scan or MRI-scan examinations that require the use of intravenous dye (contrast agent) that contains iodine. Please discuss with your doctor if you are unsure,
- if you are pregnant or breast feeding, or if you are planning to become pregnant.

Warnings and precautions

Special care should be taken with CARBUCE:

- If you suffer from impaired kidney function or any kidney disease.
- If you are scheduled for surgery.
- CARBUCE may rarely cause a condition known as lactic acidosis, which may be life-threatening. Lactic acidosis is a medical emergency. It is characterized by unexpected weight loss, nausea and vomiting, rapid breathing and stomach pains. If you suffered from this condition previously, you should tell your doctor before you start taking CARBUCE. If you develop these symptoms while using CARBUCE, please inform your doctor immediately.
- Children older than 12 years and adolescent who use CARBUCE will have to undergo periodic examinations to ensure that they are growing and developing normally.
- All patients on CARBUCE require regular clinical and blood examinations to ensure that their condition is well-controlled. All patients should continue their diabetic diet with regular meals during the day. Overweight patients should continue their energy-restricted diet.

Other medicines and CARBUCE

Always tell your healthcare provider if you are taking any other medicine (This includes all

complementary or traditional medicines).

CARBUCE could interact with other medicines and the dosages of the medicines might have to be changed by your doctor as the amounts of CARBUCE or other medicines in your blood may be affected.

In particular tell your doctor if you are taking:

- Alcohol or medicines that contain alcohol, as this may increase your risk of developing hypoglycaemia (low blood glucose levels) or lactic acidosis.
- Glucocorticosteroids, such as hydrocortisone or betamethasone, because this may make CARBUCE less effective.
- Beta-2-agonists for the treatment of asthma or chronic obstructive pulmonary (lung) disease (COPD) as this may negatively impact on the efficacy of CARBUCE.
- Diuretics (water tables) as this may make CARBUCE less effective.
- ACE-inhibitors as these medicines may lower blood glucose levels and combined use may therefore increase your risk of hypoglycaemia.
- Cimetidine, as this may affect your kidney's excretion of CARBUCE.
- Anticoagulant medication, such as warfarin, as an interaction between CARBUCE and these medicines is a possibility and the dosage of your anticoagulants may need adjustment.

CARBUCE with food, drink and alcohol

CARBUCE should be taken with or after meals.

- You should eat carbohydrates regularly throughout the day.
- You should not skip meals.
- You need to follow your doctor's/nutritionist's advice regarding your diet very carefully.

Please discuss the use of alcohol with your doctor, pharmacist or other healthcare professional.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

When your blood glucose levels fall too low, you may feel faint, dizzy, confused, sweaty and nauseous. You should not drive or use tools or machines if your blood glucose levels are too low. This can sometimes happen when CARBUCE is combined with other medicines or with insulin.

3. How to take CARBUCE

Do not share medicines prescribed for you with any other person.

Always take CARBUCE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

CARBUCE should be taken in divided doses with meals.

Adults:

- Initially, one 500 mg tablet three times a day, or one 850 mg or 1 000 mg tablet twice a day (mornings and evenings), with or after food.
- After 10 to 15 days your doctor may change the dose based on measurements of your blood glucose levels.

Children >12 years and adolescents:

- Initially, one 500 mg or one 850 mg tablet once daily, with or after meals.

- After 10 to 15 days your doctor may change the dose based on measurements of your blood glucose levels.

You should continue to take CARBUCE for as long as your doctor considers necessary.
If you have the impression that the effect of CARBUCE is too strong or too weak, talk to your doctor or pharmacist.

Elderly patients:

Your doctor will change your dose depending on your kidney function.

If you take more CARBUCE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.
You may experience an increase in side effects caused by CARBUCE such as those listed below. The most dangerous side-effect from overdosage is lactic acidosis, which can be life-threatening.

If you forget to take use CARBUCE

If you forget to take a tablet, take the missed dose right away, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking using CARBUCE

Do not stop taking CARBUCE or decrease the dose without checking with your doctor.

4. Possible side effects

CARBUCE can have side effects.

Not all side effects reported for CARBUCE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CARBUCE, please consult your healthcare provider for advice.

Tell your doctor immediately if you develop a combination of the following symptoms:
Abdominal discomfort, unexpected weight loss, nausea and vomiting, very rapid breathing that you cannot control, and stomach pain, as these are symptoms associated with the development of lactic acidosis.

Tell your doctor if you notice any of the following:
Frequent:
Headache, diarrhoea, loss of appetite, flatulence (gas), stomach discomfort, and a metallic taste in the mouth. These side-effects occur most frequently during initiation of therapy and resolve spontaneously in most cases.

Less frequent:
Other side-effects include skin rash, weight loss, and low red blood cell counts (anaemia). Some patients may experience low blood glucose levels (hypoglycaemia), especially when CARBUCE is combined with other medicines that lower blood glucose concentrations. Symptoms of hypoglycaemia include faintness, dizziness, confusion, sweating and palpitations. You may also develop reduced absorption of vitamin B12 and folic acid from your gut during long-term use of CARBUCE. Your doctor will monitor you for this.

You will have to undergo periodic blood tests to ensure that your blood glucose levels are within normal limited and that your kidneys are still functioning properly.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or

pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CARBUCE.

5. How to store CARBUCE

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Store in the original package/container.

Do not store in a bathroom.

Do not use CARBUCE after the expiry date.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CARBUCE contains:

The active substance is metformin hydrochloride. Each film-coated tablet contains 500 mg, 850 mg or 1 000 mg metformin hydrochloride.

The other ingredients are:

Anhydrous colloidal silica, hypromellose, macrogol 6000, magnesium stearate, maize starch, povidone PVP K-30, propylene glycol, purified talc, sodium starch glycolate, titanium dioxide (CI no. 77891).

What CARBUCE looks like and contents of the pack

CARBUCE 500: White coloured, intact film-coated, round, biconvex tablets scored on one side and '500' debossed on the other side. Tablets are packed in transparent/colourless PVC/PE/PVDC/aluminium blisters containing 56, 84, 90 or 112 film-coated tablets. The blister strips are packed in a printed carton.

CARBUCE 850: White coloured, intact film-coated, round, biconvex tablets plain on one side and '850' debossed on the other side. Tablets are packed in transparent/colourless PVC/PE/PVDC/aluminium blisters containing 28, 56, 60 or 84 film-coated tablets. The blister strips are packed in a printed carton.

CARBUCE 1000: White capsule-shaped, biconvex, intact film-coated tablets having central breakline on one side and plain on the other side. Tablets are packed in transparent/colourless PVC/PE/PVDC/aluminium blisters containing 60 film-coated tablets. The blister strips are packed in a printed carton.

Holder of Certificate of Registration

Strides Pharma SA (Pty) Ltd

106 16th Road

Building 2

Midrand

1685

This leaflet was last revised in

18 November 2022

Registration/Application number

CARBUCE 500: 44/21.2/0774

CARBUCE 850: 44/21.2/0775

CARBUCE 1000: 44/21.2/0776