

SCHEDULING STATUS

ACTIVATED CHARCOAL capsules, hard

Activated charcoal. Sugar free.

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.

ACTIVATED CHARCOAL is available without a doctor's prescription for you to maintain your health. Nevertheless, you still need to take ACTIVATED CHARCOAL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

- 1. What ACTIVATED CHARCOAL is and what it is used for.
- 2. What you need to know before you take ACTIVATED CHARCOAL.
- 3. How to take ACTIVATED CHARCOAL.
- 4. Possible side effects.
- 5. How to store ACTIVATED CHARCOAL.
- 6. Contents of the pack and other information.

1. What ACTIVATED CHARCOAL is and what it is used for

ACTIVATED CHARCOAL is used for severe oral poisoning, as well as drug overdoses.

2. What you need to know before you take ACTIVATED CHARCOAL

Do not take ACTIVATED CHARCOAL:

- if you suffer from kidney problems;
- if you suffer from liver problems;
- if poison was caused by strong acids, alkalis, and other corrosive (damage caused to living tissue) substances;
- if poison was caused by cyanide, iron salts and some solvents including methanol, ethanol and ethylene glycol;
- where the toxic substance has diuretic (increased passing of urine) properties or has been ingested with alcohol;
- if an immediate endoscopy (procedure to view the internal organs) is required.

Warnings and precautions

Two hours should be given before or after taking supplements or medication.

Other medicines and ACTIVATED CHARCOAL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not use ACTIVATED CHARCOAL with;

- Active oral emetics (medication to encourage vomiting) and;
- Oral antidotes (a substance to counter poisoning).

ACTIVATED CHARCOAL with food, drink and alcohol

See section 3 (How to take ACTIVATED CHARCOAL).

Pregnancy, breastfeeding and fertility

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 ACTIVATED CHARCOAL. Safety and efficacy of ACTIVATED CHARCOAL during pregnancy and breastfeeding have not been established.

Driving and using machines

ACTIVATED CHARCOAL is not likely to affect your ability in performing tasks requiring your attention.

3. How to take ACTIVATED CHARCOAL

Do not share your medicines with any other person.

Always take ACTIVATED CHARCOAL exactly as described in this leaflet, or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: Take 1 – 2 capsule/s up to 3 times daily, or as prescribed by a healthcare provider.

If you have the impression that the effect of ACTIVATED CHARCOAL is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

ACTIVATED CHARCOAL can be taken with or without food.

If you take more ACTIVATED CHARCOAL 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 the rest of the remaining ACTIVATED CHARCOAL with you so the doctor will know what you have taken.

4. Possible side effects

ACTIVATED CHARCOAL can have side effects.

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

If any of the following happens, stop taking ACTIVATED CHARCOAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ACTIVATED CHARCOAL and may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- black stools;
- constipation.

Side effects occurring with an unknown frequency:

headache.

Side effects occurring less frequent:

- hypersensitivity (allergic);
- bezoar formation (solid mass of indigestible material in your digestive tract);
- intestinal obstruction (intestinal blockage);
- intestinal perforation (when a hole forms through the intestines);
- faecal impaction (hardened stool that got stuck in the rectum or lower colon due to constipation).

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 or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form**", found online **under SAHPRA's publications**:

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

5. How to store ACTIVATED CHARCOAL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the bottle tightly closed.
- Do not use after the expiry date stated on the label or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ACTIVATED CHARCOAL contains

Each capsule contains:

The active substance is:

Activated charcoal 200 mg

The other ingredients are magnesium stearate (E570), maize starch, polyvinylpyrrolidone (E1201) and talc.

What ACTIVATED CHARCOAL looks like and contents of the pack

A hard, transparent capsule, containing a tasteless and odourless black powder. ACTIVATED CHARCOAL is packed inside a white plastic container with a white screw cap, containing a silica gel sachet. Pack size: 60 capsules.

Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd 1 Van Tonder Street Sunderland Ridge Centurion 0157 info@brunel.co.za

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

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Access to the corresponding Professional Information

The Professional Information for ACTIVATED CHARCOAL is available on <u>https://www.brunel.co.za/activated-charcoal-capsules-60/</u> or can be requested from the contact details above.

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