

SCHEDULING STATUS

S0

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**:

<https://www.sahpra.org.za/Publications/Index/8>. 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

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

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

SKEDULERINGSSTATUS

S0

ACTIVATED CHARCOAL harde kapsules

Geaktiveerde koolstof.

Suikervry.

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.

ACTIVATED CHARCOAL is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou.

Nietemin, moet jy ACTIVATED CHARCOAL versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat ACTIVATED CHARCOAL is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy ACTIVATED CHARCOAL neem.
3. Hoe om ACTIVATED CHARCOAL te neem.
4. Moontlike nuwe-effekte.
5. Hoe om ACTIVATED CHARCOAL te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat ACTIVATED CHARCOAL is, en waarvoor dit gebruik word

ACTIVATED CHARCOAL word gebruik vir erge mondelikse vergiftiging, sowel as dwelmoordosisse.

2. Wat jy moet weet voordat jy ACTIVATED CHARCOAL neem

Moet nie ACTIVATED CHARCOAL neem:

- indien jy aan enige nierprobleme ly;
- indien jy aan enige lewerprobleme ly;
- indien vergiftiging veroorsaak is deur sterk sure, alkali's en ander wegvretende stowwe;
- indien vergiftiging veroorsaak is deur sianied, ystersoute en sommige oplosmiddels insluitend metanol, etanol en etileenglikol;
- waar die toksiese stof diuretiese (verhoogde urinerings) eienskappe het of saam met alkohol ingeneem is;
- indien 'n onmiddellike endoskopie (prosedure om die interne organe te bekijk) vereis word.

Waarskuwings en voorsorgmaatreëls

Neem minstens twee ure voor of na aanvullings of medikasie.

Ander medisyne en ACTIVATED CHARCOAL

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Moet nie ACTIVATED CHARCOAL gebruik saam met:

- Aktiewe mondelinge emetikums (medikasie om braking aan te moedig) en;
- Mondelikse teengiwwe ('n middel om vergiftiging teen te werk) nie.

ACTIVATED CHARCOAL met kos, drinkgoed en alkohol

Sien afdeling 3 (**Hoe om ACTIVATED CHARCOAL te neem**).

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy ACTIVATED CHARCOAL neem.

Die veiligheid en effektiwiteit van ACTIVATED CHARCOAL tydens swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat ACTIVATED CHARCOAL jou vermoë om take uit te voer wat konsentrasie verg, sal affekteer.

3. Hoe om ACTIVATED CHARCOAL te neem

Moet nie jou medisyne met enige ander persoon deel nie.

Neem ACTIVATED CHARCOAL altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus vir jou dokter of apteker indien jy onseker is.

Die gewone dosis is:

Volwassenes: Neem 1 – 2 kapsule/s tot 3 keer per dag, of soos voorgeskryf deur 'n gesondheidsorgverskaffer.

Indien jy die indruk kry dat die uitwerking van ACTIVATED CHARCOAL te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.

ACTIVATED CHARCOAL kan met of sonder kos geneem word.

As jy meer ACTIVATED CHARCOAL geneem het as wat jy moet

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende ACTIVATED CHARCOAL saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike neue-effekte

ACTIVATED CHARCOAL kan neue-effekte hê.

Nie alle neue-effekte wat vir ACTIVATED CHARCOAL gerapporteer is, word in hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy

ACTIVATED CHARCOAL neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om ACTIVATED CHARCOAL te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige neue-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op ACTIVATED CHARCOAL gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Nuwe-effekte wat gereeld voorkom:

- swart stoelgang;
- hardlywigheid.

Nuwe-effekte wat met 'n onbekende frekwensie voorkom:

- hoofpyn.

Nuwe-effekte wat minder gereeld voorkom:

- hipersensitiwiteit (allergies);
- besoarvorming (soliede massa onverteerbare stof in jou spysvertering);
- dermobstruksie;
- dermporfasie (wanneer 'n gat deur die derm vorm);
- fekale impaksie (verharde stoelgang wat in die rektum of laer dunderm vassit weens hardlywigheid).

Indien jy enige neue-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van neue-effekte

Indien jy neue-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook neue-effekte aan SAHPRA rapporteer via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>. Deur neue-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van ACTIVATED CHARCOAL te verskaf.

5. Hoe om ACTIVATED CHARCOAL te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C.
- Hou die houer dig toe.
- Moet nie gebruik na die vervaldatum soos aangedui op die etiket of houer nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat ACTIVATED CHARCOAL bevat

Elke kapsule bevat:

Die aktiewe bestanddeel is:

Geaktiveerde koolstof 200 mg

Die ander bestanddele is magnesiumstearaat (E570), mieliestysel, polivinielpirrolidoon (E1201) en talk.

Hoe ACTIVATED CHARCOAL lyk en inhoud van die verpakking

'n Harde deursigtige kapsule met 'n smaaklose en geurlose swart poeier.

ACTIVATED CHARCOAL word verpak in 'n wit plastiekhouer met 'n wit skroefprop en 'n silikajeluitdroogmiddel.

Verpakkingsgrootte: 60 kapsules.

Houer van die Registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk

Van Tonderstraat 1

Sunderland Ridge

Centurion

0157

info@brunel.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir ACTIVATED CHARCOAL is beskikbaar by <https://www.brunel.co.za/activated-charcoal-capsules-60/> of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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