

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH ACTIVATED CHARCOAL vegecapsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegecapsule contains:

Activated Charcoal	160 mg
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Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegecapsules.

Clear vegecapsules containing a grey powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH ACTIVATED CHARCOAL supports the digestive function.

4.2 Posology and method of administration

Adults 18 years and older: Take one to two vegecapsules up to three times daily after meals.

4.3 Contraindications

- Hypersensitivity to the active ingredients or to any of the excipients listed in section 6.1.
- Patients with intestinal obstruction.

4.4 Special warnings and precautions for use

- Caution is advised in patients with decreased peristalsis.
- Activated charcoal reduces systemic exposure to many medications, including those that undergo enterohepatic recirculation, regardless of the route of administration, co-administration should be avoided.

4.5 Interaction with other medicines and other forms of interaction

- The absorptive capacity of activated charcoal may be lowered by alcohol.
- Activated charcoal may reduce the clinical effects of oral contraceptives.
- Syrup of ipecac is inactivated by activated charcoal.
- Activated charcoal reduces systemic exposure to many medications (e.g. acetaminophen, aminophylline, amiodarone, atenolol, carbamazepine, dapsone, digoxin, disopyramide, fluoxetine, indomethacin, moxifloxacin, nadolol, phenytoin, phenobarbital, piroxicam, quinine, sotalol, theophylline, tricyclic antidepressants, valproate, and verapamil), including those that undergo enterohepatic recirculation, regardless of the route of administration, co-administration should be avoided.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH ACTIVATED CHARCOAL does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: constipation, black stools, abdominal pain, bloating, flatulence.

Frequency unknown: gastrointestinal obstruction.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions 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>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.13 Other.

5.1 Pharmacodynamic properties

LOCAL HEALTH ACTIVATED CHARCOAL supports the digestive function.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on LOCAL HEALTH ACTIVATED CHARCOAL.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch

Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

White plastic bottle with a white plastic lid.
Pack size: 60 vegecapsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for CJ Distribution

23 Stag Road, Glen Austin, Johannesburg, South Africa

careline@cjdsa.com

010 589 2729

www.localhealth.com

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

**PATIENT INFORMATION LEAFLET
SCHEDULING STATUS**

SO

LOCAL HEALTH ACTIVATED CHARCOAL (vegecapsules)

Each vegecapsule contains:

Activated Charcoal	160 mg
Sugar free	

Complementary Medicine: Other (Health Supplement)

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH ACTIVATED CHARCOAL with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

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

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

LOCAL HEALTH ACTIVATED CHARCOAL supports the digestive function.

2. What you need to know before you use LOCAL HEALTH ACTIVATED CHARCOAL

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Do not use LOCAL HEALTH ACTIVATED CHARCOAL:

- If you are hypersensitive (allergic) to any of the ingredients listed in section 6.
- If you have an intestinal obstruction.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH ACTIVATED CHARCOAL, especially if you have a medical condition.

Consult a healthcare practitioner prior to use:

- If you have decreased peristalsis.

Children and adolescents

LOCAL HEALTH ACTIVATED CHARCOAL is not recommended for individuals below the age of 18 years.

Other medicines and LOCAL HEALTH ACTIVATED CHARCOAL

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use if you are taking any other medication, as LOCAL HEALTH ACTIVATED CHARCOAL can alter their effectiveness.

Consult a healthcare practitioner prior to use if you are taking any of the following: oral contraceptives, ipecac, alcohol.

Activated charcoal reduces systemic exposure to many medications (e.g. acetaminophen, aminophylline, amiodarone, atenolol, carbamazepine, dapsone, digoxin, disopyramide, fluoxetine, indomethacin, moxifloxacin, nadolol, phenytoin, phenobarbital, piroxicam, quinine, sotalol, theophylline, tricyclic antidepressants, valproate, and verapamil), including those that undergo enterohepatic recirculation, regardless of the route of administration, co-administration should be avoided.

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 practitioner for advice before using LOCAL HEALTH ACTIVATED CHARCOAL.

Driving and using machinery

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH ACTIVATED CHARCOAL does not adversely affect their performance.

3. How to use LOCAL HEALTH ACTIVATED CHARCOAL

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH ACTIVATED CHARCOAL exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults 18 years and older

Take one to two vegecapsules up to three times daily after meals, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH ACTIVATED CHARCOAL can have side effects. Not all side effects reported for LOCAL HEALTH ACTIVATED CHARCOAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH ACTIVATED CHARCOAL, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH ACTIVATED CHARCOAL and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH ACTIVATED CHARCOAL. You may need urgent medical attention or hospitalisation.

Frequent: constipation, black stools, abdominal pain, bloating, flatulence.

Frequency unknown: gastrointestinal obstruction.

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

Reporting of side effects

If you experience side effects, inform 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: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH ACTIVATED CHARCOAL.

5. How to store LOCAL HEALTH ACTIVATED CHARCOAL

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Store in the original container and keep the container tightly sealed.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH ACTIVATED CHARCOAL to your pharmacist.
- Do not dispose of unused LOCAL HEALTH ACTIVATED CHARCOAL in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH ACTIVATED CHARCOAL contains

Each vegecapsule contains:

Activated Charcoal	160 mg
Other ingredients: maize starch, magnesium stearate.	
Sugar free	

Presentation and identification of LOCAL HEALTH ACTIVATED CHARCOAL

Clear vegecapsules containing a grey powder, packed into a white plastic container with a white plastic lid.

Pack size: 60 vegecapsules.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685

Careline: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

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**PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS**

SO

LOCAL HEALTH ACTIVATED CHARCOAL (vegecapsules)

Elke vegecapsule bevat:

Geaktiveerde Houtskool	160 mg
Suikervry	

Komplementêre Medisyne: Ander (Gesondheidsaanvulling)

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

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

LOCAL HEALTH ACTIVATED CHARCOAL is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH ACTIVATED CHARCOAL versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie LOCAL HEALTH ACTIVATED CHARCOAL met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

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

1. Wat LOCAL HEALTH ACTIVATED CHARCOAL is en waarvoor dit gebruik word

LOCAL HEALTH ACTIVATED CHARCOAL ondersteun die spysverteringsfunksie.

2. Wat u moet weet voordat u LOCAL HEALTH ACTIVATED CHARCOAL gebruik

'n Gevarieerde dieet is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamstelling, sowel as geestelike en fisiese prestasie te behaal.

Moet nie LOCAL HEALTH ACTIVATED CHARCOAL neem nie:

- Indien u hipersensitief (allergies) is vir enige van die bestanddele gelys in afdeling 6.
- Indien u 'n intestinale obstruksie het.

Waarskuings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH ACTIVATED CHARCOAL gebruik, veral as u 'n mediese toestand het.

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u verminderde peristalse het.

Kinders en adolessente

LOCAL HEALTH ACTIVATED CHARCOAL word nie aanbeveel vir individue onder die ouderdom van 18 jaar nie.

Die neem van LOCAL HEALTH ACTIVATED CHARCOAL en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige ander medikasie gebruik, aangesien LOCAL HEALTH ACTIVATED CHARCOAL hul doeltreffendheid kan verander. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige van die volgende neem: orale voorbehoedmiddels, ipecac, alkohol.

Geaktiveerde houtskool verminder sistemiese blootstelling aan baie medikasie (bv. asetaminofen, aminofilien, amiodaroon, atenolol, karbamazepien, dapsone, digoksien, disopyramied, fluoksetien, indometasien, moksifloksasien, nadolol, fenitoin, fenobarbital, pirosikaam, kinien, sotalol, teofilien, trisikliese antidepressante, valproaat en verapamil), insluitend dié wat enterohepatiese hersirkulasie ondergaan, ongeag die toedieningsroete, moet geklytidge toediening vermy word.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u LOCAL HEALTH ACTIVATED CHARCOAL gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH ACTIVATED CHARCOAL nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH ACTIVATED CHARCOAL te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH ACTIVATED CHARCOAL presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes 18 jaar en ouer

Neem een tot twee vegecapsules tot en met drie maal daagliks na maaltye, of soos aanbeveel deur u gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH ACTIVATED CHARCOAL kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH ACTIVATED CHARCOAL is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van LOCAL HEALTH ACTIVATED CHARCOAL, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik van LOCAL HEALTH ACTIVATED CHARCOAL en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal: swelling van u hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejeuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie teen LOCAL HEALTH ACTIVATED CHARCOAL gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Dikwels: hardlywigheid, swart stoelgange, buikpyn, opgeblasenheid, winderigheid.

Dikwelsheid onbekend: gastroïntestinale obstruksie.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van LOCAL HEALTH ACTIVATED CHARCOAL.

5. Hoe om LOCAL HEALTH ACTIVATED CHARCOAL te bêre

- Beskerm teen vog en bère by of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Stoor in die oorspronklike verpakking en hou die houder dig verseël.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH ACTIVATED CHARCOAL na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH ACTIVATED CHARCOAL in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH ACTIVATED CHARCOAL bevat

Elke vegecapsule bevat:	
Geaktiveerde Houtskool	160 mg
Ander bestanddele: mieliestysel, magnesiumstearaat.	
Suikervry	

Aanbieding en identifikasie van LOCAL HEALTH ACTIVATED CHARCOAL

Deursigtige vegecapsules wat 'n grys poeier bevat, verpak in 'n wit plastiekhouer met 'n wit plastiek deksel.

Verpakkingsgrootte: 60 vegecapsules.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685

Sorglyn: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.