

ASHWAGANDHA



PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

WELLVITA® ASHWAGANDHA 500 mg VEGGIE CAPSULES

Sugar free

Category D 33.6 Western herbal

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.

WELLVITA ASHWAGANDHA is available without a doctor's prescription for you to maintain your health. Nevertheless you still need to use WELLVITA ASHWAGANDHA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share WELLVITA ASHWAGANDHA with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What WELLVITA ASHWAGANDHA is and what it is used for:

WELLVITA ASHWAGANDHA, a powerful adaptogenic herb, is known for calming and balancing properties and the ability to enhance the body's resilience to stress. It also possesses potent antioxidant properties that help fight cellular damage caused by free radicals

2. What you need to know before you use WELLVITA ASHWAGANDHA:

Do not take WELLVITA ASHWAGANDHA:

- If you are hypersensitive (allergic) to any of the ingredients (including excipients) in the formulation listed in section 6;
- If you are pregnant or breastfeeding;
- Do not use in children, unless under medical supervision

Warnings and precautions:

Special care should be taken with WELLVITA ASHWAGANDHA:

- If you are taking any prescribed medication (including benzodiazepines, levothyroxine and immunosuppressants);
 - If you suffer from auto-immune diseases (such as lupus, rheumatoid arthritis, etc) as this medicine might cause the immune system to become more active;
 - Before going for any scheduled surgery as this medicine might slow the central nervous system (stop taking this medicine at least 2 weeks before any scheduled surgery);
 - If you are taking medication for diabetes or hypertension as Ashwagandha can interfere with blood sugar levels as well as blood pressure;
 - If you have a stomach ulcer or liver problems;
 - When you suffer from any serious ailments or conditions (such as porphyria, diabetes, thyroid disorders, stomach ulcers, liver problems or hypertension);
- Consult your healthcare provider before taking this medicine.

Other medicines and WELLVITA ASHWAGANDHA:

Always tell your health care provider if you are taking any other medicine (including warfarin and immunosuppressants) before taking this medicine. This includes all complementary or traditional medicines.

WELLVITA ASHWAGANDHA with food:

Capsules can be taken with or without food. Avoid alcohol while taking this product.

Pregnancy and breastfeeding:

Do not take if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.

Driving and using machinery:

It is not always possible to predict to what extent WELLVITA ASHWAGANDHA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities requiring mental alertness, judgement and / or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines / equipment until they are aware of the measure to which WELLVITA ASHWAGANDHA affects them.

3. How to take WELLVITA ASHWAGANDHA:

Do not share medicines prescribed for you with any other person. Always take WELLVITA ASHWAGANDHA exactly as described in the leaflet or as your doctor, pharmacist or other health care provider has told you to use it. You should check with your doctor, pharmacist or other health care provider if you are unsure.

The usual dose for adults is one capsule daily.

- Take the capsule with a glass of water without regards to a meal.
- Do not exceed the recommended dose.
- Take your capsule at the same time each day for the best results. It will also help you remember when to take the capsule.
- To open the container, push down on the child proof lid and turn as illustrated on the lid.

If you take more WELLVITA ASHWAGANDHA than you should:

In the event of overdose, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take WELLVITA ASHWAGANDHA:

Always take WELLVITA ASHWAGANDHA as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

WELLVITA ASHWAGANDHA can have side effects. Not all side effects reported for WELLVITA ASHWAGANDHA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking WELLVITA ASHWAGANDHA, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking WELLVITA ASHWAGANDHA and tell your doctor 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;
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to WELLVITA ASHWAGANDHA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Stomach upset;
- Vomiting;
- Rash or itching.

In rare cases Ashwagandha can cause liver issues.

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

Reporting side effects:

If you get side effects, talk to your health care provider. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA publications: <https://www.sahpra.org.za/-Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of WELLVITA ASHWAGANDHA.

5. How to store WELLVITA ASHWAGANDHA:

- Store all medicines out of reach of children.
- Store in a cool, dry place below 25° C.
- Do not freeze.
- Keep away from direct sunlight.
- Keep the container tightly closed.
- Do not store in the bathroom.
- Do not use after the expiry date stated on the container.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information:

What WELLVITA ASHWAGANDHA contains:

The active substances, per veggie capsule, are: *Withania somnifera* L. [(Ashwagandha), root as 500 mg of a 15:1 extract] 500 mg and *Piper nigrum* [(Black pepper), fruit as 5 mg of an extract standardised to 95% piperine] 5 mg.

The other ingredients are: Magnesium stearate, silicon dioxide and veggie capsule.

Contains no sugar.

What WELLVITA ASHWAGANDHA looks like and contents of the pack:

30 Veggie capsules are packed in a plastic container. The capsules are white.

Applicant of Certificate of Registration:

Alveta Healthcare (Pty) Ltd, 1 Greenwich Grove, Station Road, Rondebosch, 7700. Company registration number: 2004/021899/07. Pharmacy audit number: Y60123.

The leaflet was last revised in: August 2023

Access to the corresponding Professional Information:

Professional information is electronically available at www.wellvita.co.za. Customer care number: 0861 999 004

ASHWAGANDHA



PASIËNTINLIGTINGSBLAD:

SKEDULERINGSSTATUS: S0

WELLVITA® ASHWAGANDHA 500 mg VEGGIE KAPSULES
Suikervry

Kategorie D 33.6 Westerse kruie

Komplementêre medisyne - Gesondheidsaanvulling

Hierdie ongeregisteerde medisyne is nie deur die SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

Lees hierdie voulibjet deeglik want dit bevat belangrike inligting vir jou.

WELLVITA ASHWAGANDHA is beskikbaar sonder 'n voorskrif om 'n geringe kwaal te behandel. Maar jy moet nogsteeds WELLVITA ASHWAGANDHA versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voulibjet; jy mag dit dalk weer moet lees.
- Moenie WELLVITA ASHWAGANDHA deel met enige ander persoon nie.
- Vra jou apteker of gesondheidsorg verskaffer indien jy meer inligting of advies benodig.

Wat is in hierdie inligtingsblad

1. Wat WELLVITA ASHWAGANDHA is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy WELLVITA ASHWAGANDHA begin gebruik
3. Hoe om WELLVITA ASHWAGANDHA te gebruik
4. Moontlike nuwe-effekte
5. Hoe om WELLVITA ASHWAGANDHA te bêre
6. Inhoud van die verpakking en meer inligting

1. Wat WELLVITA ASHWAGANDHA is en waarvoor dit gebruik word:

WELLVITA ASHWAGANDHA, 'n kragtige adaptogeniese kruie, is bekend vir kalmerende en balanserende eienskappe sowel as die vermoë om die liggaam se veerkragtigheid teen stres te verbeter. Dit beskik ook oor kragtige antioksidant-eienskappe wat help om sellulêre skade wat deur vry radikale veroorsaak word, te beveeg.

2. Wat jy moet weet voordat jy WELLVITA ASHWAGANDHA begin gebruik:

Moenie WELLVITA ASHWAGANDHA gebruik:

- As jy hipersensitief (allergies) is vir enige van die bestanddele (insluitend onaktiewe bestanddele) in die formulering gelys in afdeling 6 nie;
- Indien jy swanger is of borsvoed nie;
- In kinders nie, tensy onder mediese toesig.

Waarskuwings en voorsorgmaatreëls:

Spesiale sorg moet geneem word met WELLVITA ASHWAGANDHA:

- As jy enige voorgeskrewe medikasie gebruik (insluitend bensodiasepiene, levotiroksien en immuunonderdrukkers);
 - As jy aan auto-immuun siektes (soos lupus, rumatoïede artritis, ens.) ly, aangesien hierdie medisyne die immuunstelsel meer aktief kan maak;
 - Voordat jy vir enige geskeduleerde operasie gaan, aangesien hierdie medisyne die sentrale senuweestelsel kan vertraag (hou op om hierdie medisyne te gebruik ten minste 2 weke voor enige geskeduleerde operasie);
 - As jy medikasie neem vir diabetes of hipertensie aangesien Ashwagandha met bloedsuikervlakke sowel as bloeddruk kan inmeng;
 - As jy 'n maagseer of lewerprobleme het;
 - Wanneer jy aan enige ernstige kwale of toestande ly (soos porfirie, diabetes, skildklierafwykings, maagseer, lewerprobleme of hipertensie);
- Raadpleeg u gesondheidsorgverskaffer voordat u hierdie medisyne gebruik.

Andere medisyne en WELLVITA ASHWAGANDHA:

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne (insluitend warfarin en immuunonderdrukkers) neem voordat jy hierdie medisyne neem. Dit sluit alle komplementêre of tradisionele medisyne in.

WELLVITA ASHWAGANDHA met kos:

Kapsules kan met of sonder kos geneem word. Vermy alkohol as jy hierdie produk gebruik.

Swangerskap, borsvoeding en vrugbaarheid:

Moenie gebruik as jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê.

Bestuur en gebruik van masjinerie:

Dit is nie altyd moontlik om te voorspel tot watter mate WELLVITA ASHWAGANDHA met daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie betrokke raak by aktiwiteite wat geestelike waaksaamheid, oordeel en/of gesonde koördinasie en visie vereis nie, bv. ry, vlieg, seil, bestuur van masjiene en/of toerusting, totdat hulle weet tot watter mate WELLVITA ASHWAGANDHA hulle beïnvloed.

3. Hoe om WELLVITA ASHWAGANDHA te gebruik:

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem WELLVITA ASHWAGANDHA altyd presies soos voorgeskryf in die pamflet of soos jou dokter, apteker of ander gesondheidsorgverskaffer jou aanbeveel het om dit te gebruik. Raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer indien jy onseker is. Die gewone dosis vir volwassenes is een kapsule per dag.

- Neem die tablet met 'n glas water sonder inagneming van 'n maaltyd.
- Moenie die aanbevole dosis oorskry nie.
- Neem jou kapsule elke dag op dieselfde tyd vir die beste resultate. Dit sal jou ook help om te onthou wanneer om die kapsule te neem.
- Om die houertjie te maak, druk af op die deksel en draai terselfdertyd soos geïllustreer bo-op die deksel.

As jy meer WELLVITA ASHWAGANDHA neem as wat jy moes:

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

As jy vergeet om WELLVITA ASHWAGANDHA te neem:

Neem altyd WELLVITA ASHWAGANDHA soos voorgeskryf. As jy 'n dosis mis, neem dit so gou as moontlik. As jy nie die gemiste dosis onthou totdat dit tyd is vir die volgende dosis nie, slaan die gemiste dosis oor en gaan aan met jou normale doseringskedule. Moenie 'n dubbele dosis neem om vergeete individuele dosisse in te haal nie.

4. Moontlike nuwe-effekte:

WELLVITA ASHWAGANDHA kan nuwe-effekte hê. Nie alle nuwe-effekte is in die voulibjet ingesluit nie. Indien jy enige onaangename nuwe-effekte ervaar of voel dat jou algemene gesondheid verswak, hou onmiddellik op om die produk te gebruik en kontak jou geneesheer.

As jy enige van die volgende simptome ervaar, hou onmiddellik op om WELLVITA ASHWAGANDHA te gebruik en kontak dadelik jou dokter of gaan na die ongevalle afdeling van die naaste hospitaal:

- Swelling van hande, voete, enkels, gesig, lippe, keel of mond wat dit moeilik maak om te sluk of asem te haal;
- Flou val.

Hierdie is alles ernstige nuwe-effekte en jy mag dringend hulp benodig.

Rapporteer die volgende nuwe-effekte aan jou geneesheer:

- Omgekrapte maag;
- Braking;
- Uitslag of gejeuk.

In seldsame gevalle kan Ashwagandha lewerprobleme veroorsaak.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter of apteker in kennis.

Rapportering van nuwe-effekte:

As jy nuwe-effekte kry, praat met jou gesondheidsorgverskaffer. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", aanlyn gevind onder SAHPRA publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van WELLVITA ASHWAGANDHA te verskaf.

5. Hoe om WELLVITA ASHWAGANDHA te bêre:

- Berg alle medisyne buite bereik van kinders.
- Berg in 'n koel, droë plek onder 25°C.
- Moenie die medisyne vries nie.
- Hou weg van direkte sonlig.
- Hou die houertjie dig toe.
- Moenie in die badkamer bêre nie.
- Moenie gebruik na die vervaldatum op die produk nie.
- Moenie ongebruikte medisyne in die drein gooi nie (bv. in die toilet).
- Bring alle ongebruikte medisyne na jou apteker toe.

6. Inhoud van die verpakking en meer inligting:

Wat WELLVITA ASHWAGANDHA bevat:

Die aktiewe bestanddele, per veggie kapsule, is: *Withania somnifera* L. [(Ashwagandha), wortel as 500 mg van 'n 15:1-ekstrak] 500 mg en *Piper nigrum* (Swartpeper), vrugte as 5 mg van 'n uitgetrekte gestandaardiseerde tot 95% piperiesin] 5 mg. Die ander bestanddele is: Magnesiumstearaat, silikondioksied en veggie kapsule. Bevat geen suiker nie.

Hoe lyk WELLVITA ASHWAGANDHA en inhoud van die verpakking:

30 Veggie kapsules word in 'n plastiekhouer verpak. Die kapsules is wit.

Aansoeker van Sertifikaat van Registrasie:

Alveta Healthcare (Pty) Ltd, Greenwich Grove 1, Stasieweg, Rondebosch, 7700. Maatskappyregistrasienommer: 2004/021899/07. Apteker ouditnommer: Y60123.

Die pamflet is laas hersien in: Augustus 2023

Toegang tot die ooreenstemmende professionele inligting:

Professionele inligting is elektronies beskikbaar by www.wellvita.co.za. Kliëntediensnommer: 0861 999 004