# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S0

## GENOLOGIX ASHWAGANDHA 500mg hard capsules

Ashwagandha root extract 500 mg per daily dose (2 capsules, each containing 250 mg), equivalent to 7 500 mg of dried root

Sugar free

**COMPLEMENTARY MEDICINE**

**Ayurveda**

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

This leaflet is also available in Afrikaans on the product pages at https://genologix.co.za/product/genologix-ashwagandha-500mg-30-days-supply/ (30-day pack) and https://genologix.co.za/product/genologix-ashwagandha-500mg-bulk-120-days-supply/ (120-day pack).

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

Genologix Ashwagandha 500mg is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Genologix Ashwagandha 500mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Genologix Ashwagandha 500mg 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 Genologix Ashwagandha 500mg is and what it is used for
2. What you need to know before you take Genologix Ashwagandha 500mg
3. How to take Genologix Ashwagandha 500mg
4. Possible side effects
5. How to store Genologix Ashwagandha 500mg
6. Contents of the pack and other information


## 1. What Genologix Ashwagandha 500mg is and what it is used for

Genologix Ashwagandha 500mg is an Ayurvedic herbal medicine. It contains an extract of the root of ashwagandha (Withania somnifera).

Genologix Ashwagandha 500mg:

- is traditionally used in Ayurveda as a Rasayana (rejuvenating tonic) to support general vitality;
- is traditionally used to help the body cope with stress; and
- is traditionally used to support restful sleep when stress interferes with relaxation.

If sleeplessness lasts for more than 4 weeks, consult your health care provider.

## 2. What you need to know before you take Genologix Ashwagandha 500mg

**Do not take Genologix Ashwagandha 500mg:**

- if you are hypersensitive (allergic) to ashwagandha (Withania somnifera) or any of the other ingredients of Genologix Ashwagandha 500mg (listed in section 6).
- if you are pregnant.

**Warnings and precautions**

Take special care with Genologix Ashwagandha 500mg. Talk to your doctor or pharmacist before taking it:

- if you have a thyroid condition or take thyroid medicine, because ashwagandha may increase thyroid hormone levels;
- if you have liver disease or have had liver problems;
- if you have an autoimmune condition, such as rheumatoid arthritis, lupus or multiple sclerosis;
- if you have a hormone-sensitive condition, such as prostate cancer;
- if you have diabetes or low blood pressure;
- if you are going to have an operation, because ashwagandha may add to the effect of anaesthetics. Stop taking it 2 weeks before planned surgery; or

- if you take any of the medicines listed under “Other medicines and Genologix Ashwagandha 500mg”.

**Children and adolescents**

Do not give Genologix Ashwagandha 500mg to children and adolescents under 18 years of age. Its safety in this age group has not been established.

**Other medicines and Genologix Ashwagandha 500mg**

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

Talk to your doctor or pharmacist before you take Genologix Ashwagandha 500mg if you take:

- medicine for diabetes, because blood sugar may drop too low;
- medicine for high blood pressure, because blood pressure may drop too low;
- sedatives or sleeping tablets (e.g. benzodiazepines), or other medicines that make you drowsy;
- thyroid hormone medicine;
- medicine that suppresses the immune system (e.g. after a transplant).

**Genologix Ashwagandha 500mg with food, drink and alcohol**

Avoid alcohol while taking Genologix Ashwagandha 500mg, because it may increase drowsiness.

**Pregnancy, breastfeeding and fertility**

Do not take Genologix Ashwagandha 500mg if you are pregnant. Consult your health care provider before you take it if you are breastfeeding; its safety during breastfeeding has not been established.

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 health care provider for advice before taking this medicine.

**Driving and using machines**

Genologix Ashwagandha 500mg may make some people drowsy. Take care when driving, operating machinery or doing tasks that need you to be alert.

It is not always possible to predict to what extent Genologix Ashwagandha 500mg may interfere with your daily activities. Do not drive, operate machinery or take part in activities that need you to be alert until you know how Genologix Ashwagandha 500mg affects you.

**Genologix Ashwagandha 500mg contains**

Genologix Ashwagandha 500mg contains no sugar and no sweeteners.

## 3. How to take Genologix Ashwagandha 500mg

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

Always take Genologix Ashwagandha 500mg exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Adults (18 years and older):** take two (2) capsules a day, split into two doses: one (1) capsule in the morning and one (1) capsule in the evening. This provides 500 mg of ashwagandha root extract a day.

**Do not take more than two (2) capsules in 24 hours.**

**Children and adolescents under 18 years:** Genologix Ashwagandha 500mg is not intended for this age group.

**How to take it:**

1. Take one capsule in the morning and one in the evening.
2. Swallow each capsule whole with a glass of water.
3. Stop taking Genologix Ashwagandha 500mg if you get any side effects (see section 4).

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

**If you take more Genologix Ashwagandha 500mg than you should**

If you take too many capsules, you may feel very drowsy or get stomach upset, nausea or diarrhoea.

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

**If you forget to take Genologix Ashwagandha 500mg**

If you forget a dose, take your next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Genologix Ashwagandha 500mg**

You can stop taking Genologix Ashwagandha 500mg at any time. No withdrawal effects are expected.

## 4. Possible side effects

Genologix Ashwagandha 500mg can have side effects.

Not all side effects reported for Genologix Ashwagandha 500mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Genologix Ashwagandha 500mg, please consult your health care provider for advice.

If any of the following happens, stop taking Genologix Ashwagandha 500mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the 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 reaction to Genologix Ashwagandha 500mg. You may need urgent medical attention or hospitalisation.

Stop taking Genologix Ashwagandha 500mg and see your doctor immediately if you notice signs of liver problems:

- yellowing of the skin or the whites of the eyes,
- dark urine or pale stools,
- itching, unusual tiredness, loss of appetite or pain in the upper right part of the stomach.

Liver problems have been reported in a small number of people taking ashwagandha.

Tell your doctor if you notice any of the following:

**Frequency unknown:**

- drowsiness,
- stomach upset or stomach pain,
- nausea (feeling sick),
- diarrhoea.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Genologix Ashwagandha 500mg.

You can also report side effects directly to Genologix by completing the side effect report form on our website at https://genologix.co.za/adr-form-page/, or by contacting us on 087 094 0594, WhatsApp 060 532 8317 or info@genologix.co.za.

## 5. How to store Genologix Ashwagandha 500mg

**Store all medicines out of reach of children.**

- Store in a cool, dry place at or below 25 °C.
- Protect from light and moisture.
- Keep the capsules in the original pouch. Reseal the pouch tightly after each use.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the pouch.
- Do not use Genologix Ashwagandha 500mg if the pouch seal is broken or the capsules look damaged.

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 Genologix Ashwagandha 500mg contains

The active substance is an extract of ashwagandha root (Withania somnifera), standardised to withanolides 5 %.

| Active ingredient | Per capsule (dried herb equivalent) | Per daily dose, 2 capsules (dried herb equivalent) |
|---|---|---|
| Withania somnifera (L.) Dunal (ashwagandha) [root, as 250 mg per capsule (500 mg per dose) of a 15:1 extract standardised to withanolides 5 %] | 3 750 mg | 7 500 mg |

The other ingredients are microcrystalline cellulose, magnesium stearate and hypromellose (the vegan capsule shell).

Microcrystalline cellulose is a plant fibre used as a filler. It makes sure that every capsule contains the correct amount of the active ingredient. Magnesium stearate is a common ingredient in foods and medicines. A very small amount is used to help the powder flow smoothly through our production machines. These ingredients are not active ingredients. They are only used to help us make the capsules accurately and consistently.

### What Genologix Ashwagandha 500mg looks like and contents of the pack

Clear, hard vegan (hypromellose) capsules filled with a pale brown to brown powder.

The powder in the capsules comes from natural plant material, so its colour can vary from batch to batch. It may be lighter or darker. This is normal. It is caused by natural factors such as soil conditions, rainfall and the time of harvest. It does not affect the quality of the product.

Genologix Ashwagandha 500mg is available in two pack sizes: 60 capsules (30 daily doses) and 240 capsules (120 daily doses). Both are packed in a resealable, laminated, light-protective pouch.

### Holder of Certificate of Registration

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### Registration number

Not applicable. Unregistered complementary medicine, Act 101/1965.

### Access to the corresponding Professional Information

The Professional Information for Genologix Ashwagandha 500mg is available on request from Genologix on 087 094 0594 or info@genologix.co.za. Address your correspondence for the attention of the Responsible Pharmacist.