PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GENOLOGIX VALERIAN EXTRACT 300mg hard capsules

Valerian (Valeriana officinalis) root extract (5:1) 300 mg per capsule, standardised to 0,8% valeric acid
Sugar free

COMPLEMENTARY MEDICINE
Western Herbal Medicine
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

This leaflet is also available in Afrikaans at https://genologix.co.za/product/genologix-valerian-300mg-30-days-supply/

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

Genologix Valerian Extract 300mg is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Genologix Valerian Extract 300mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Genologix Valerian Extract 300mg 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 Valerian Extract 300mg is and what it is used for
2. What you need to know before you take Genologix Valerian Extract 300mg
3. How to take Genologix Valerian Extract 300mg
4. Possible side effects
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6. Contents of the pack and other information

1. What Genologix Valerian Extract 300mg is and what it is used for

Genologix Valerian Extract 300mg is a Western herbal medicine. It contains an extract of the root of the valerian plant (*Valeriana officinalis* L.).

Genologix Valerian Extract 300mg:

- is traditionally used for the relief of mild symptoms of mental stress and to aid sleep.

If symptoms persist or get worse after 2 weeks of continued use, consult a doctor or other health care provider.

2. What you need to know before you take Genologix Valerian Extract 300mg

Do not take Genologix Valerian Extract 300mg:

- if you are hypersensitive (allergic) to valerian or any of the other ingredients of Genologix Valerian Extract 300mg (listed in section 6).

Warnings and precautions

Take special care with Genologix Valerian Extract 300mg. Talk to your doctor or pharmacist before taking it:

- if you have liver disease;
- if you take sleeping tablets, sedatives, or medicines for anxiety, depression or epilepsy;
- if you are going to have an operation. Stop taking it at least 2 weeks before surgery;
- if you take any other medicine prescribed by your doctor.

Children and adolescents

Do not give Genologix Valerian Extract 300mg to children and adolescents under 18 years of age. Its safety in this age group has not been established.

Other medicines and Genologix Valerian Extract 300mg

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

Valerian may add to the effects of:

- sleeping tablets and sedatives (e.g. benzodiazepines such as diazepam, or zolpidem);
- other medicines that cause drowsiness (e.g. some antihistamines, opioid painkillers);
- alcohol.

Talk to your doctor or pharmacist before taking it if you use any of these medicines, or other medicines that are broken down by the liver.

Genologix Valerian Extract 300mg with food, drink and alcohol

Genologix Valerian Extract 300mg can be taken with or without food. Do not drink alcohol while taking it, as this may increase drowsiness.

Pregnancy, breastfeeding and fertility

The safety of Genologix Valerian Extract 300mg in pregnancy and breastfeeding has not been established. Genologix Valerian Extract 300mg is not recommended during pregnancy or breastfeeding.

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 Valerian Extract 300mg may impair your ability to drive and use machines. If you are affected, do not drive or operate machinery.

It is not always possible to predict to what extent Genologix Valerian Extract 300mg 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 Valerian Extract 300mg affects you.

Genologix Valerian Extract 300mg contains

Genologix Valerian Extract 300mg contains no sugar and no sweeteners.

3. How to take Genologix Valerian Extract 300mg

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

Always take Genologix Valerian Extract 300mg 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) – **for mild symptoms of mental stress:** take one (1) capsule at any time during the day.

Adults (18 years and older) – **to aid sleep:** take up to two (2) capsules half an hour to one hour before going to bed.

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

Children and adolescents under 18 years: Genologix Valerian Extract 300mg is not intended for this age group.

How to take it:

1. Swallow the capsules whole with a glass of water.
2. Valerian may take 2 to 4 weeks of continued use to reach its full effect.
3. Stop taking Genologix Valerian Extract 300mg 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 Valerian Extract 300mg than you should

If you take too many capsules, you may get tiredness, abdominal cramps, chest tightness, light-headedness, hand tremor or dilated pupils. These usually pass within 24 hours. If they do not, contact your doctor.

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 Valerian Extract 300mg

If you forget a dose, skip it and take your next dose at the usual time. Do not take a double dose.

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

If you stop taking Genologix Valerian Extract 300mg

You can stop taking Genologix Valerian Extract 300mg at any time. No withdrawal effects are expected.

4. Possible side effects

Genologix Valerian Extract 300mg can have side effects.

Not all side effects reported for Genologix Valerian Extract 300mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Genologix Valerian Extract 300mg, please consult your health care provider for advice.

If any of the following happens, stop taking Genologix Valerian Extract 300mg 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 Valerian Extract 300mg. You may need urgent medical attention or hospitalisation.

yellowing of the skin or eyes, dark urine or pain in the upper abdomen (signs of liver problems, reported very rarely with valerian).

Tell your doctor if you notice any of the following:

Frequency unknown:

- nausea (feeling sick) or abdominal cramps,
- drowsiness the next morning,
- dizziness or headache.

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 Valerian Extract 300mg.

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 Valerian Extract 300mg

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 Valerian Extract 300mg 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 Valerian Extract 300mg contains

The active substance is a dry extract of valerian root (*Valeriana officinalis* L., radix).

Active ingredient	Per capsule	Per 2 capsules (maximum daily dose)
Valeriana officinalis (valerian) root extract (5:1), equivalent to 1 500 mg dried root per capsule, standardised to 0,8% valeric acid	300 mg	600 mg

The other ingredients are microcrystalline cellulose 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. These ingredients are not active ingredients. They are only used to help us make the capsules accurately and consistently.

What Genologix Valerian Extract 300mg looks like and contents of the pack

Clear, hard vegan (hypromellose) capsules filled with a yellow-brown to brown powder. Valerian has a strong, characteristic smell. This is normal.

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.

30 capsules 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 Valerian Extract 300mg 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.