PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GENOLOGIX SAW PALMETTO EXTRACT 300mg hard capsules

Saw palmetto (Serenoa repens) fruit extract (15:1) 300 mg per daily dose (1 capsule), standardised to 25% total fatty acids

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-saw-palmetto-300mg-bulk-120-days-supply/

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

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

- Keep this leaflet. You may need to read it again.
- Do not share Genologix Saw Palmetto 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 Saw Palmetto Extract 300mg is and what it is used for
2. What you need to know before you take Genologix Saw Palmetto Extract 300mg
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1. What Genologix Saw Palmetto Extract 300mg is and what it is used for

Genologix Saw Palmetto Extract 300mg is a Western herbal medicine for adult men. It contains an extract of the berries of the saw palmetto palm (*Serenoa repens*), standardised to its natural fatty acids.

Genologix Saw Palmetto Extract 300mg:

- is traditionally used in Western herbal medicine to support prostate and urinary health in men.

Before using it for urinary symptoms, see a doctor to rule out serious conditions.

If complaints worsen or if symptoms such as fever, spasms, blood in the urine, painful urination or urinary retention occur, consult a doctor or a qualified health care practitioner.

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

Do not take Genologix Saw Palmetto Extract 300mg:

- if you are hypersensitive (allergic) to saw palmetto or any of the other ingredients of Genologix Saw Palmetto Extract 300mg (listed in section 6).
- if you are a woman, a child or an adolescent under 18 years. There is no relevant use in these groups.

Warnings and precautions

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

- if you have urinary symptoms that have not been checked by a doctor;
- if you take medicine that thins the blood (e.g. warfarin);
- if you take hormone medicines (e.g. finasteride, dutasteride, testosterone);
- if you have low blood pressure;
- if you are going to have an operation. Stop taking it at least 2 weeks before surgery.

Children and adolescents

Do not give Genologix Saw Palmetto 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 Saw Palmetto Extract 300mg

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

A few cases of suspected interactions with warfarin have been reported, with increased INR values. Talk to your doctor if you take warfarin or other medicines that thin the blood (e.g. aspirin, clopidogrel).

Saw palmetto may affect hormone medicines. Talk to your doctor or pharmacist before you take it if you take:

- finasteride or dutasteride (medicines for the prostate or hair loss);
- testosterone or other hormone treatments.

Genologix Saw Palmetto Extract 300mg with food, drink and alcohol

Take Genologix Saw Palmetto Extract 300mg with food. Stomach upset is more likely when it is taken on an empty stomach.

Pregnancy, breastfeeding and fertility

Genologix Saw Palmetto Extract 300mg is for men only. Women must not take it, especially during pregnancy or breastfeeding, or if they use oestrogen-containing medicines or hormonal contraceptives.

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 Saw Palmetto Extract 300mg is not expected to affect your ability to drive or use machines.

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

Genologix Saw Palmetto Extract 300mg contains

Genologix Saw Palmetto Extract 300mg contains no sugar and no sweeteners.

3. How to take Genologix Saw Palmetto Extract 300mg

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

Always take Genologix Saw Palmetto 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.

Adult men (18 years and older): take one (1) capsule once a day with food.

Do not take more than one (1) capsule in 24 hours.

Women, children and adolescents under 18 years: Genologix Saw Palmetto Extract 300mg is not intended for these groups.

How to take it:

1. Take the capsule with a meal.
2. Swallow the capsule whole with a glass of water.
3. Stop taking Genologix Saw Palmetto 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 Saw Palmetto Extract 300mg than you should

If you take too many capsules, you may get nausea, an upset stomach 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 Saw Palmetto Extract 300mg

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

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

If you stop taking Genologix Saw Palmetto Extract 300mg

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

4. Possible side effects

Genologix Saw Palmetto Extract 300mg can have side effects.

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

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

Tell your doctor if you notice any of the following:

Frequency unknown:

- nausea (feeling sick), vomiting, diarrhoea or abdominal pain (especially when taken on an empty stomach),
- allergic reactions (e.g. rash, itching),
- 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 Saw Palmetto 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 Saw Palmetto 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 Saw Palmetto 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 Saw Palmetto Extract 300mg contains

The active substance is a dry extract of saw palmetto fruit (*Serenoa repens* (W. Bartram) Small, fructus), standardised to 25% total fatty acids.

Active ingredient	Per capsule	Per daily dose (1 capsule)
Serenoa repens (saw palmetto) fruit extract (15:1), equivalent to 4 500 mg dried fruit, standardised to 25% total fatty acids	300 mg	300 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 Saw Palmetto Extract 300mg looks like and contents of the pack

Clear, hard vegan (hypromellose) capsules filled with a white to off-white 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.

120 capsules (120 daily doses) packed in a resealable, laminated, light-protective pouch.

Holder of Certificate of Registration

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This leaflet was last revised on

11 November 2026

Registration number

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

Access to the corresponding Professional Information

The Professional Information for Genologix Saw Palmetto 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.