PATIENT INFORMATION LEAFLET

PROSTASAN®

SCHEDULING STATUS:

S0

A.VOGEL PROSTASAN®, capsules
Saw palmetto (*Serenoa repens/Sabal serrulata*) fruit
Contains sugar as sugar-alcohols
Sorbitol 70 %: 6,92 – 8,46 mg per capsule

COMPLEMENTARY MEDICINE
Western Herbal Medicine
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
A.VOGEL PROSTASAN® is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use A.VOGEL PROSTASAN® carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share A.VOGEL PROSTASAN® with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 8 weeks.

What is in this leaflet

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

1. What A.VOGEL PROSTASAN® is and what it is used for

A.VOGEL PROSTASAN® is a herbal medicine to help manage and prevent benign prostatic hypertrophy (BPH), which is a non-cancerous enlargement of the prostate.

It also helps with related symptoms like urinary problems and sexual dysfunction. These symptoms include:
- Pain or discomfort when urinating
- Needing to urinate often at night or during the day
- Difficulty starting urination or feeling like you can't fully empty your bladder
- Weak urine flow
- Dribbling after urination
- Sexual difficulties related to BPH, e. g. erectile and ejaculatory difficulties

2. What you need to know before you take A.VOGEL PROSTASAN®

Do not take A.VOGEL PROSTASAN®
- If you are hypersensitive (allergic) to *Serenoa repens* fruit (Saw palmetto) or any of the other ingredients of A.VOGEL PROSTASAN® (listed in section 6).

Warnings and precautions
Take special care with A.VOGEL PROSTASAN®
- Before you take A.VOGEL PROSTASAN® for the first time, your health care provider should ensure that you don't have any other serious conditions.
- If the condition worsens or does not improve after 8 weeks, consult your health care provider.
- If symptoms are accompanied by blood in the urine or fever, please seek medical advice urgently.
- If you have liver or kidney problems, tell your health care provider before taking A.VOGEL PROSTASAN®.

A.VOGEL PROSTASAN® is indicated for use in adult males only. It is not intended for use by women.

Children and adolescents
A.VOGEL PROSTASAN® is indicated for use in adult males only. It is not intended for use by children and adolescents under 18 years.

Other medicines and A.VOGEL PROSTASAN®
Always tell your health care provider if you are taking any other medicines. (This includes complementary or traditional medicines.) There are no known interactions with other medicines.

Pregnancy and breastfeeding
Do not take A.VOGEL PROSTASAN®, it is not intended for use by women. 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 A.VOGEL PROSTASAN®.

Driving and using machines
No impairment of the ability to drive or use machines is known.

A.VOGEL PROSTASAN® contains sorbitol
A.VOGEL PROSTASAN® contains 6,92 to 8,46 mg sorbitol 70 % in each capsule.

3. How to take A.VOGEL PROSTASAN®

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

Always take A.VOGEL PROSTASAN® exactly as described in this leaflet or as your doctor, pharmacist or other health care provider has told you. Check with your doctor, pharmacist or other health care provider if you are not sure.

Adults (males, 18 years and over)
The usual dose is one (1) capsule daily. Take the capsules with water, with a meal. Minor stomach upsets (see section 4) may be avoided by taking it with a meal.

A.VOGEL PROSTASAN® can be taken over a long period. However, if the symptoms persist for longer than 8 weeks, or become worse, you should consult a health care provider.

If you take more A.VOGEL PROSTASAN® than you should
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 a dose of A.VOGEL PROSTASAN®
If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

A.VOGEL PROSTASAN® can have side effects. Side effects, e.g. allergic reactions, are possible when taking medicine, including A.VOGEL PROSTASAN®.

Not all side effects reported for A.VOGEL PROSTASAN® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking A.VOGEL PROSTASAN®, please consult your health care provider for advice.

If any of the following happens, stop taking A.VOGEL PROSTASAN® and tell your doctor immediately or go to the casualty department at your nearest hospital:
- An allergic reaction, e.g. swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching.

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

Tell your doctor if you notice any of the following
Less frequent side effects
- Burping and stomach discomfort
- Rash, itchy skin (pruritus)

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, pharmacist or other health care provider. 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 A.VOGEL PROSTASAN®.
In addition, side-effects can also be reported to info@pharmacorp.co.za.

5. How to store A.VOGEL PROSTASAN®

Store all medicines out of reach of children.
- Store at or below 25 °C, in a dry place
- Store in the original packaging
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle

6. Contents of the pack and other information

What A.VOGEL PROSTASAN® contains
The active substance is Saw palmetto fruit
Each capsule contains
Serenoa repens (BARTRAM) SMALL = *Sabal serrulata* (MICHAUX) NICHOLS (Saw palmetto) 320 mg
[Dried fruit, 9 – 12:1 extract providing 2,9 – 3,8 g dry plant equivalent]

The other ingredients are ferric oxide black, ferric oxide red, ferric oxide yellow, gelatin (porcine), glycerol, sorbitol 70 % and water, purified.

What A.VOGEL PROSTASAN® looks like and contents of the pack
Oval-shaped, dark brown coloured soft capsules containing a clear, green-brown coloured oil.

Contents of the pack
Amber glass bottles, closed with pilfer proof screw caps, or blister strips, packed in an outer carton.
Pack sizes: 28 or 30 capsules
Not all pack sizes may be marketed

Holder of Certificate of Registration
PHARMACORP (PTY) LTD
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Registration number
To be allocated

Access to the corresponding Professional Information
(and the translated Patient Information Leaflet)
www.avogel.co.za

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