

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Prostasan** soft capsules Saw Palmetto soft extract

**Read all of this leaflet carefully before you start taking this product because it contains important information for you.**

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 8 weeks.

#### **What is in this leaflet:**

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

### **1. WHAT PROSTASAN IS AND WHAT IT IS USED FOR**

Prostasan is a traditional herbal medicinal product containing the extract of Saw Palmetto fruit. It is used to relieve urinary discomfort in men with an enlarged prostate (also known as benign prostatic hyperplasia or BPH). This is exclusively based on long-standing use.

Used to help relieve symptoms including:

- The need to urinate frequently (especially at night)
- Weak or interrupted urinary flow
- A feeling that you cannot empty your bladder completely

This product is used to treat an enlarged prostate in men over 18. The prostate gland is found just below the bladder in men. As men get older this gland may enlarge causing urinary discomfort.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROSTASAN**

### **Do not take Prostasan**

- If you are allergic to:
  - Saw Palmetto fruit. This product contains Saw Palmetto fruit.
  - Any of the other ingredients of this product (listed in Section 6).

### **Warnings and precautions**

- This product is for use in men only. It is not suitable for use in women, children or adolescents under 18 years of age.
- Before taking this product you should visit your doctor to make sure your symptoms are caused by an enlarged prostate and not by any serious underlying condition.
- Talk to your doctor or pharmacist if:
  - Your symptoms of urinary discomfort worsen, persist or do not improve within 8 weeks
  - You have blood in your urine
  - You have pain when passing urine
  - You have difficulty passing urine
  - You have a fever or chills
  - You have pain in your back You have pain or spasms in your groin
  - You are due to undergo surgery

### **Children and adolescents**

- Do not give this product to children or adolescents under 18 years of age.

### **Other medicines and Prostasan**

- If you are taking medication for an enlarged prostate talk to your doctor before taking this product. It may not be suitable for you.
- If you are taking warfarin do not take this product.
- If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as Prostasan.

### **Pregnancy and breast-feeding**

- Do not take this product. It is for use in men only.

### **Driving and using machines**

- This product has no known effect on your ability to drive or use machines. Make sure you know how this product affects you before you drive or use machinery.

### **Prostasan contains sorbitol**

- This medicine contains 7.7 mg sorbitol in each capsule.

## **3. HOW TO TAKE PROSTASAN**

Always take this product exactly as described in the leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

**Adults and older people:** Take one capsule daily with food.

For oral use only.

Enough data has not been gathered to establish the safety of this product for long term use.

### **If you take more Prostasan than you should**

- If you take too much and feel ill, talk to your doctor.

### **If you forget to take Prostasan**

- Do not worry about a missed dose. Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product ask your doctor, pharmacist or nurse.

## **4. POSSIBLE SIDE EFFECTS**

Like all products, this product can cause side effects, although not everybody gets them.

### **Side effects**

#### **Digestive symptoms**

- Feeling sick (nausea)
- Digestive upsets such as sickness or diarrhoea
- Stomach discomfort

Stop taking this product if you find these are troubling you. Talk to your doctor, pharmacist or nurse if you are concerned.

These side effects are more likely to occur if this product is taken on an empty stomach. This product should be taken with food.

These side effects are uncommon and likely to affect less than 1 in every 100 people.

**Other**

- Allergic reactions such as skin rashes
- Headache

Stop taking this product if these occur.

It is not known how frequently these side effects may occur.

**Remember to see your doctor if:**

- Your symptoms of urinary discomfort worsen, persist or do not improve within 8 weeks
- You have blood in your urine
- You have pain when passing urine
- You have difficulty passing urine
- You have a fever or chills
- You have pain in your back
- You have pain or spasms in your groin

**Reporting of side effects**

- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You can also report side effects directly via:  
HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL – Dublin 2  
Tel: +353 6764971  
Fax: +353 6762517  
Website: <http://www.imb.ie/> www.hpra.ie  
E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)
- By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE PROSTASAN**

- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in appearance. The capsules should be dark brown in colour.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Prostasan contains

Each capsule contains 320 mg of extract (as soft extract) from Saw Palmetto fruit (*Serenoa repens* (Bartram) Small fructus (*Sabal serrulata* (Michaux) Nichols fructus)) (9-12:1). Extraction solvent: Ethanol 96% V/V.

The other ingredients used for the capsule shell are gelatin, glycerol, liquid sorbitol (non-crystallising), iron oxide (red, black and yellow) and purified water.

### What Prostasan looks like and the contents of the pack

Prostasan capsules are soft, oval-shaped and dark brown in colour. Prostasan is available in packs containing 30, 60 or 90 capsules. Not all pack sizes may be marketed.

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This leaflet was last revised in 07/2022.

### **What is Saw Palmetto?**

Saw Palmetto is a plant which is native to sub-tropical regions of the United States. It produces berries (fruits) and it is the extract of these berries which is used to make this product.

### **You should also know**

- Your doctor may have done a blood test for prostate specific antigen (PSA). It is unlikely that this product will alter your levels of PSA.
- This product is not suitable for vegetarians.

A.Vogel Ireland runs a helpline by phone and email which can provide you with further information.

E-mail: [enquiries@avogel.ie](mailto:enquiries@avogel.ie)

Phone: 0818 930 070

You can get a larger print or audio version of this leaflet. Call this number:  
0818 930 070