



Patient Information Leaflet



Prostasan®
Saw Palmetto capsules



21920 Prostasan PIL UK Variation RFI July 2012 alt1.indd 1

Information

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

This medicine is available without prescription. However, before using Prostasan you must have been told by your doctor that you have an enlarged prostate (also known as benign prostatic hypertrophy or BPH). You need to take Prostasan carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you need more information or advice ask your doctor, pharmacist or other qualified healthcare practitioner.
- You must contact a doctor, pharmacist or qualified healthcare practitioner if your symptoms worsen.
- If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please tell your doctor, pharmacist or qualified healthcare practitioner.

In this leaflet:

1. What the product is and what it is used for
2. Before you take this product
3. How to take this product
4. Possible side effects
5. How to store this product
6. Further information

1. What the product is for

Prostasan is a traditional herbal medicinal product used to relieve urinary discomfort in men with an enlarged prostate (also known as benign prostatic hypertrophy or BPH). This is based on traditional use only.

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.

An enlarged prostate is also known as BPH. The prostate gland is found just below the bladder in men. As men get older this gland may enlarge causing urinary discomfort.

Do's and Don'ts

2. Before you take this product

- You must have been told by your doctor that you have BPH.
- This product is not suitable for anyone under 18 years of age.

Do not take this product if you are allergic to:

- Saw palmetto fruit. This product contains Saw palmetto fruit.
- Any of the other ingredients of this product. (See Section 6 Further Information)

Take special care with this product – see your doctor if:

- Your symptoms of urinary discomfort worsen or do not improve within 8 weeks.
- You have blood in your urine
- You have a fever
- You have difficulty passing urine
- You have been told by your doctor that you have an intolerance to some sugars. This product contains sorbitol and may not be suitable for you.

If you are due to undergo surgery

- Tell your doctor you are taking this product.

Taking other medicines

- If you are taking medication for an enlarged prostate talk to your doctor before using this product. It may not be suitable for you.
- You can use this product with any other medicines.

Taking this product with food and drink

- You can eat and drink as normal whilst using this product.

Pregnancy and breast-feeding

- Do not use 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 it affects you before you drive or use machinery.

Using

3. How to take this product

Adults and the elderly: Take one capsule daily with food.

You can take Prostasan for as long as is necessary.

If symptoms worsen consult a doctor as soon as possible.

However you must consult a doctor immediately if you have:

- Blood in your urine
- A fever
- Difficulty passing urine

If no improvement in symptoms is seen after 8 weeks of treatment consult your doctor for further advice.

Not for use in children or those under 18.

For oral use only.

If you take more of this product than you should

- If you take too much and feel ill, talk to your doctor. Taking too much is unlikely to be harmful.

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Using

If you forget to take this product

- Don't worry about the missed dose. Take the next capsule as usual.

If you stop taking this product

- You can stop taking this product at any time.

There is additional information in Section 6 at the end of this leaflet.



Side effects

4. Possible side effects

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

Minor side effects

The following minor side effects can occur when using this product.

Digestive symptoms

- Belching
- Stomach discomfort

Skin reactions

- Rash
- Itching (pruritis)

Discontinue use if you find these are troubling you.

The frequency of these side effects is not known. This means it is not known how often these reactions occur as there have not been enough reports to allow this information to be calculated.

If you are concerned about any side effect, if a side effect becomes serious or if you notice a side effect not listed in this leaflet, please tell your doctor, pharmacist or qualified healthcare practitioner.

If you feel this product isn't working:

- If symptoms worsen consult a doctor as soon as possible.
- See your doctor immediately if you have:
 - Blood in your urine
 - A fever
 - Difficulty passing urine
- If no improvement is seen after 8 weeks treatment consult your doctor for further advice.



Information

5. How to store this product

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

6. Further Information

What this product contains

1 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, sorbitol, iron oxide (red, black and yellow) and purified water.

1 capsule contains 7.7 mg sorbitol.

What this product looks like and the contents of the pack

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

Traditional Herbal Registration Holder and Manufacturer

Traditional Herbal Registration Holder and Batch Release:

Bioforce (UK) Ltd,
2 Brewster Place,
Irvine KA11 5DD

Manufacturer:

Bioforce AG, CH-9325, Roggwil
Switzerland

THR No. 13668/0011



Certification Mark

This leaflet was revised on 07/2012

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.

Bioforce runs a helpline by phone and email which can provide you with further information.

Email: enquiries@avogel.co.uk

Phone: 0845 608 5858

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your doctor's surgery or pharmacy, or call freephone 0800 100 3352 (available 10am-2pm Monday-Friday).

You can get a larger print or audio version of this leaflet.

Call this number:
0845 608 5858.

