



Dear Customer,

Thank you for your interest in **Prostasan**<sup>®</sup> Saw Palmetto capsules and for downloading these information pages for your doctor.

This pack contains a summary on the use of Saw Palmetto herb in the treatment of an enlarged prostate (BPH), as well as technical information on **Prostasan**<sup>®</sup> Saw Palmetto capsules, a registered (licensed) herbal medicine.

Your doctor may find these pages useful when giving you advice as to whether Saw Palmetto herb can be a suitable treatment for you to try. If however, you have any questions, please call our helpline at the number below.

**Prostasan**<sup>®</sup> is available without a prescription, from pharmacies and health food stores. It is a traditional herbal medicinal product for use in the relief of lower urinary tract symptoms in men with a confirmed enlarged prostate (BPH), exclusively based upon long-standing use as a traditional remedy. You do not need to inform your doctor before using **Prostasan**<sup>®</sup>, unless you are already taking another medicine for enlarged prostate, but always read the patient-information-leaflet (found in each pack) first.

Feel free to contact the A.Vogel Herbal Helpline **0845 608 5858** or email us at **enquiries@bioforce.co.uk**

Best wishes

**Prostasan**<sup>®</sup> Support Team

**Bioforce (UK) Ltd**

Brewster Place, Irvine KA11 5DD  
Telephone: 01294 277344 • Facsimile: 01294 277922  
enquiries@Bioforce.co.uk • www.AVogel.co.uk

Pioneer in Natural Health  
– since 1923

A stylized signature of A.Vogel in a cursive script.



Dear Doctor

Thank you for reviewing this information on **Prostasan**<sup>®</sup> Saw Palmetto capsules – a traditional herbal medicinal product used for the symptomatic relief of urinary symptoms of BPH.

This pack contains:

- A clinical summary of the use of Saw Palmetto in BPH taken from the book '*A guide to the use of Saw Palmetto in BPH for healthcare professionals*'. A full copy is available on request.
- Prescribing information for **Prostasan**<sup>®</sup> Saw Palmetto capsules, a copy of the PIL (patient-information-leaflet) and SmPC.

**Prostasan**<sup>®</sup> Saw Palmetto is a licensed traditional herbal medicine for use in men with a confirmed diagnosis of BPH. It can be a treatment to consider in the following situations:

- Men with mild symptoms of BPH as an alternative to 'watchful waiting'
- Men with mild to moderate symptoms of BPH unable to tolerate  $\alpha$ -blockers or  $\alpha$ -reductase inhibitors

**Prostasan**<sup>®</sup> is a THR product and the indication given is based exclusively on evidence of traditional use of Saw Palmetto fruit as a herbal medicine rather than on data generated from clinical trials. However, this does not mean that no clinical trial data is available for Saw Palmetto fruit or **Prostasan**<sup>®</sup>. The clinical summary contains generic information for Saw Palmetto available in research journals and the public domain. While some studies report negative results, many have been positive and point to the efficacy of Saw Palmetto in the treatment of BPH.

The minor side effects that may arise from use of **Prostasan**<sup>®</sup> Saw Palmetto are most likely to be belching and minor stomach discomfort, or allergies to the herb. Full information is contained in the enclosed SmPC.

For further information on how **Prostasan**<sup>®</sup> Saw Palmetto can benefit your patients, please contact our helpline on **0845 608 5858** or email **enquiries@bioforce.co.uk**

Yours sincerely

**Prostasan**<sup>®</sup> Support Team

**Bioforce (UK) Ltd**

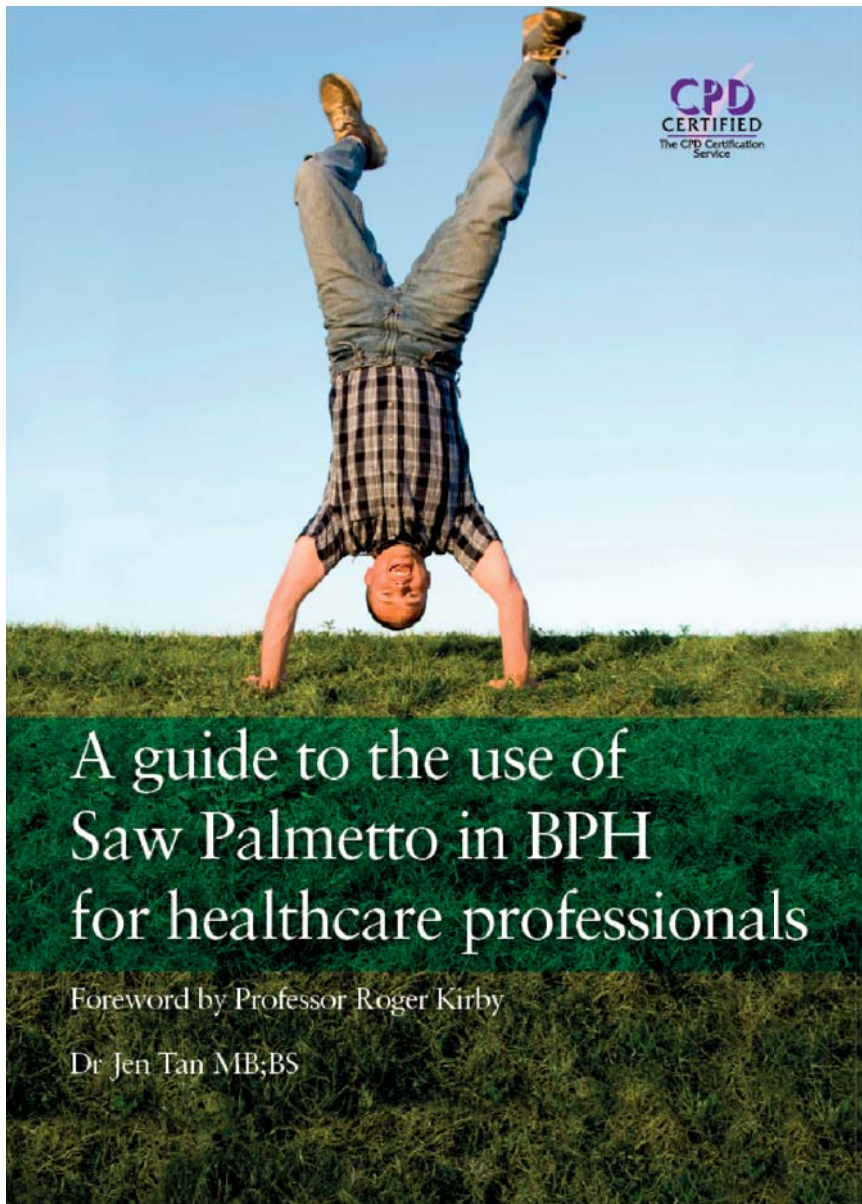
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# Clinical Summary

Taken from the book 'A guide to the use of Saw Palmetto in BPH for healthcare professionals'



For a complimentary copy of the book, email your request to [enquiries@bioforce.co.uk](mailto:enquiries@bioforce.co.uk) or phone 0845 608 5858.

## Foreword

**Professor Roger Kirby MA MD FRCS FEBU**

*Director, The Prostate Centre, London.*

In an age when patients are looking to embrace all forms of treatment, including alternative medicine, for a variety of medical complaints it is particularly appropriate that a book such as this is available to outline the significance of one particular herbal medicine—saw palmetto. The science of phytotherapy has advanced considerably during the last decade and many herbal preparations are now recognized as accepted treatments for various conditions especially for those seeking to reduce the use of conventional drugs. However, as always, it is essential to separate the empirical data from the anecdotal evidence, which has previously been the cornerstone of claims for the efficacy of herbal medicines.

This publication aims to outline clearly the weight of evidence which is available to support the use of saw palmetto in the treatment of BPH. The position of herbal medicines in the therapeutic spectrum has been further strengthened by the introduction of a regulatory framework by the MHRA. The Traditional Herbal Medicine Registration Scheme (THMRS) provides healthcare professionals with support for the therapeutic benefits of specific herbal compounds. Saw palmetto was one of the first traditional herbal medicines to gain such a licence approval in the form of the Prostan product from A.Vogel and I believe that this accreditation supports the weight of evidence which exists, detailing the safety and effectiveness of this herb in the treatment of BPH.

The reduction in patient morbidity and the need to minimize invasive procedures are key targets in the treatment of BPH. The inclusion of saw palmetto on the list of acceptable remedies for this particular condition will be welcomed by patients. It provides the clinician with a useful alternative to other treatment methodologies and enables the medical practitioner to provide a full range of options.

I am certain that all those involved in the management of BPH will be able to benefit from the information contained in this publication.



### PROFESSOR ROGER KIRBY

Professor Kirby is an internationally recognized authority on prostate cancer, benign prostatic hyperplasia and erectile dysfunction.

Professor Kirby qualified from the University of Cambridge in 1975 with a distinction in surgery. He became a consultant at St Bartholomew's Hospital in 1986 and nine years later moved to St George's Hospital where he was awarded a personal chair in Urology and also became Director of Post-Graduate Education. is now Visiting Professor both at St George's and at the Institute of Urology, London.

He has performed more than 1500 radical prostatectomy operations and is the most experienced prostate surgeon in the UK. He has written over 50 books and 200 academic papers, is founder and Editor of the journal Prostate Cancer and Prostatic Diseases and Associate Editor of the British Journal of Urology International. He is an associate member of the American Urological Association; Secretary of the British Urological Foundation and Chairman of the Prostate Research Campaign UK.

He has personally raised over £3m for prostate and urological charities, through activities ranging from marathon running to mountain climbing.

Taken from the book;

*'A guide to the use of Saw Palmetto in BPH for healthcare professionals'*



## What is saw palmetto?

### BOTANY

Saw palmetto (also known as *Sabal serrulata*, *Serenoa repens* or Dwarf Palm) belongs to the family of betel palm plants and is native to the southern coastal states of North America, Central America, and tropical South America.

The low-stemmed palm grows from a creeping rootstock and forms leafstalks of up to 1.5m in length. The characteristic fan-shaped, serrate leaves are split into as many as twenty-four segments. The plant bears olive-sized, dark red, bluish or black berries or fruit containing the pharmacologically active ingredients<sup>1</sup> and this is the part of the plant used medicinally.

### CONSTITUENTS

Like all herbal products, saw palmetto extracts contain a number of active substances. These may be summarized as<sup>2</sup>:

#### Carbohydrates

Invert sugar, mannitol, high molecular weight polysaccharides (>MW 100 000).

#### Fixed oils

Free fatty acids and their glycerides. Monoacylglycerides. Oleic acid, capric acid, caproic acid, caprylic acid, lauric acid, myristic acid, palmitic acid, and stearic acid.

#### Steroids

$\beta$ -sitosterol, campesterol, stigmasterol, and other steroidal compounds.

#### Other constituents

Flavonoids, carotene, resins, tannins, and volatile oils.

## Pharmacology of saw palmetto

### INHIBITION OF 5 $\alpha$ -REDUCTASE

Saw palmetto extracts have been shown to reduce the activity of the 5 $\alpha$ -reductase which catalyses the conversion of testosterone into its active metabolite DHT<sup>3,4,5,6</sup>. This leads to a lowering of DHT level and involution of the glandular epithelial of the prostate<sup>20</sup>. *In-vitro* experiments have documented an inhibitory effect on 5 $\alpha$ -reductase activity in epithelial tissue and stroma of human hyperplastic prostate. Two isoforms of 5 $\alpha$ -reductase exist—both are expressed in healthy prostatic tissue and in the pathologically altered prostate<sup>7</sup>. Whilst the 5 $\alpha$ -reductase inhibitor finasteride only inhibits isoform II<sup>23</sup>, extracts of saw palmetto appear to act as an efficient inhibitor of both isoforms<sup>24</sup>. This effect has also been demonstrated in human foreskin<sup>8,9,10</sup> a tissue with a high 5 $\alpha$ -reductase content<sup>3</sup>.

Saw palmetto exerts its 5 $\alpha$ -reductase inhibition without influencing the secretion of PSA (prostate specific antigen), suggesting that it will not interfere with the use of this marker substance<sup>11</sup>.

### INHIBITION OF ANDROGENIC BINDING

*In-vitro* studies in rat prostatic tissue and human foreskin fibroblasts have demonstrated that saw palmetto extracts competitively inhibit the binding of DHT to androgen receptor sites<sup>9</sup>. The acid lipophilic fraction of saw palmetto appears to have a selective anti-androgenic effect on the prostate without affecting the hypothalamic-pituitary axis or Leydig cells<sup>12,3,13</sup>. Clinically this could explain the absence of the 'hormonally related' undesirable effects such as gynaecomastia and loss of libido which are a part of the other anti-androgenic therapies, as these affect the higher-ranking hormonal regulatory systems<sup>12,14</sup>.

Taken from the book;

'A guide to the use of Saw Palmetto in BPH for healthcare professionals'



# The case for saw palmetto in the treatment of the BPH

## AIMS OF TREATING BPH

For most men suffering from an enlarged prostate, the aim of treatment should be to improve of LUTS (lower urinary tract symptoms) and quality of life.

Clinical progression of BPH is indicated by worsening of symptoms, rather than the development of severe or life-threatening complications (such as acute urinary retention) or the need of surgery<sup>15</sup>. Hence, a conservative approach to management of BPH presents few inherent risks.

This is where saw palmetto can fit in as one of the treatment options for BPH.

## SAW PALMETTO AS AN ALTERNATIVE TO 'WATCHFUL WAITING'

Conventionally, treatment options start with watchful waiting. A significant proportion of men with lower urinary tract symptoms do not have a clinically enlarged prostate. If symptoms are mild, both patient and clinician would often prefer to avoid the potential side-effects associated with conventional medication such as  $\alpha$ -antagonists or  $5\alpha$ -reductase inhibitors.

As the side-effect profile of saw palmetto is favourable (with reported adverse events equivalent to those seen with placebo<sup>16</sup>), it can present a relatively 'risk-free' alternative to watchful waiting in men where some form of treatment is the preferred option but, when the potential side-effects of conventional medication presents a barrier to treatment.

## SAW PALMETTO AS AN ALTERNATIVE TO CONVENTIONAL MEDICATION

It is clear that conventional drugs used for BPH ( $\alpha$ -antagonists,  $5\alpha$ -reductase inhibitors, anti-cholinergics) are associated with a number of side-effects which many men would prefer to avoid. This is particularly so for side-effects such as erectile dysfunction and gynaecomastia.

There is now an increasingly convincing body of evidence which suggests that saw palmetto can present an alternative to conventional medication, particularly in those with mild to moderate BPH.

For instance, **a trial comparing the efficacy of finasteride against saw palmetto<sup>17</sup> showed**

that both treatments decreased symptoms of BPH equally. However, saw palmetto gave rise to fewer adverse events and had no effect on serum PSA levels. Significantly more men in the finasteride group withdrew from the study.

Taken from the book;

*'A guide to the use of Saw Palmetto in BPH for healthcare professionals'*





## The clinical evidence

**The clinical evidence available from controlled studies provides evidence that saw palmetto is efficacious in mild to moderate BPH with minimal side-effects.**

The results of more than twenty-two controlled studies involving saw palmetto have been published since 1983, including trials with placebo and comparator drug controls (two compared the efficacy of saw palmetto against finasteride).

Of these, data from eighteen were included in a systematic review by Wilt et al.<sup>16</sup>. This found that saw palmetto improved symptoms of BPH and urodynamic flow measures to an extent comparable with finasteride.

In ten placebo controlled studies, saw palmetto reduced nocturia by 25% absolute difference (-0.76 times per evening) vs placebo (95%CI, -1.21 to -0.31). Overall, 242 out of 329 men in six studies using saw palmetto reported an improvement in symptoms compared with 168 men out of 330 using placebo ( $p < 0.001$ ).

In two comparative studies against finasteride, saw palmetto was found to provide a 37% improvement in IPSS scores from baseline against 40% for finasteride (95% CI, -0.45 to 1.19).

**Saw palmetto was found to be superior to placebo and comparable to finasteride in improving peak and mean urine flow rates and reducing residual volume.**

In eight studies, weighted mean difference for peak urine flow was 1.93ml/s, representing an absolute improvement of 24% over placebo (95% CI, 0.72 to 3.14). In two studies comparing saw palmetto against finasteride, the weighted mean difference for peak urine flow was -0.74 ml/s (95% CI, -1.66 to 0.18).

The weighted difference in mean urine flow was found in four studies to be 2.22 ml/s, an absolute improvement of 28% over placebo (95% CI, 1.17 to 3.27). Against finasteride, it was found to be -0.40ml/s in one study (95% CI, 0.15 to 0.95).

Weighted mean difference in residual volume was found in six studies to be -22.05 ml, representing a 43% absolute decrease against placebo (95% CI, -40.78 to -3.32) and 5.70ml against finasteride (95% CI, -5.42 to 16.82) in one study.

Wilt reported adverse events to be 'mild and comparable with placebo'.

A study by Debruyne<sup>18</sup> looked at the effects of saw palmetto compared to tamsulosin in 704 patients over a period of 12 months and found similar efficacy. Mean IPSS scores before treatment were found to be 15.2 and 15.5 in the tamsulosin and saw palmetto groups respectively. These decreased by 4.4 in each group (95% CI, -8.89 to 0.90). Peak urinary flow rates decreased by similar amounts - 1.79ml/s and 1.89ml/s for saw palmetto and tamsulosin respectively ( $p = 0.79$ ).

### CLINICAL TRIALS OF PROSTASAN

A multi-centre study using A.Vogel's saw palmetto capsules (Prostasan) recruited men experiencing symptoms of BPH<sup>19</sup>. A total of eighty-five Doctors treated 364 men with BPH who had not previously been treated using any form of medication, for a total of 8 weeks. Patients were allocated to three groups based on the severity of symptoms as measured by the IPSS.

**IPSS at the first follow-up (4 weeks) improved by an average of 35%, regardless of the severity of baseline symptoms.**

The mildest symptom group improved by 42%, the medium symptom group by 38%, and those with severe symptoms, by 30%.

Quality of life (due to urinary problems) scores also improved, with patients progressing from "somewhat dissatisfied" with their urinary problems to overwhelmingly "satisfied" after 8 weeks.

Taken from the book;

*'A guide to the use of Saw Palmetto in BPH for healthcare professionals'*



## REFERENCES

- 1 Wagner H. Pharmazeutische Biologie 2: Drogen and ihre Inhaltsstoffe. Gustav Fischer Verlag Stuttgart, New York, 5th Edition 1993: 348.
- 2 Barnes J, Anderson AA, Phillipson JD, Herbal Medicines, third edition, 521
- 3 Schweikert HU et al. J Clin. Invest. 1989; 83: 662-68.
- 4 Pannunzio E, d'Ascenco R, et al. Journal of Urology 1987; 137 (226a): Abstract 491.
- 5 Carilla E, Briley M, et al. J. Steroid. Biochem 1984; 20: 521 – 23.
- 6 Koch E, Biber A. Urologie 1994; 34: 90 – 95.
- 7 Habib FK et al. J Endocrinol 1998; 156: 509 – 517.
- 8 Hagenlocher M et al. Aktuelle Urologie 1993; 24: 146 – 49.
- 9 Düker EM et al. Inhibition of 5- $\mu$ -reductase activity by extracts from Sabal serrulata, Planta Med 1989; 55: 587.
- 10 Sultan C et al. J Steroid Biochem 1984; 20: 515-19.
- 11 Bayne CW et al. Serenoa repens: a 5 $\alpha$ -reductase types I and II inhibitor - new evidence in a coculture model of BPH. Prostate 1999; 40: 232-241.
- 12 Klippel KF. Dtsch Apoth Ztg 1993; 133(27): 2488.
- 13 Mattei F, et al. The conservative therapy of BPH with Saw palmetto extract. TW Urologie Nephrologie 1990; 2(5): 346-350.
- 14 Casarosa C et al. Clinical Therapeutics 1988; 10 (5): 585 – 88.
- 15 Kondas J, et al. Sabal serrulata extract (Strogen forte) in the treatment of symptomatic benign prostatic hyperplasia. Int Urol Nephrol 1996; 28(6): 767-772.
- 16 Wilt T et al. Saw palmetto extracts for the treatment of benign prostatic hyperplasia. JAMA 1998; 280(18): 1604-1609.
- 17 Wilt TJ, A, Stark G, MacDonald R, Lau J, Mulrow C. Saw Palmetto extracts for treatment of benign prostatic hyperplasia. A systematic review. JAMA, 1998; 280(18);1604-9.
- 18 Carraro J-C, et al. Comparison of Phytotherapy (Permixon) with finasteride in the treatment of benign prostate hyperplasia. The Prostate 1996; 29: 231-240.
- 19 Riedi E et al. Natural Treatment of BPH. ARS MEDICI 2. 2005 3.
- 20 Graf P. ArzteWoche 1995; 2: 9.

Taken from the book;

*'A guide to the use of Saw Palmetto in BPH for healthcare professionals'*





# Prostasan<sup>®</sup>

# Product Information

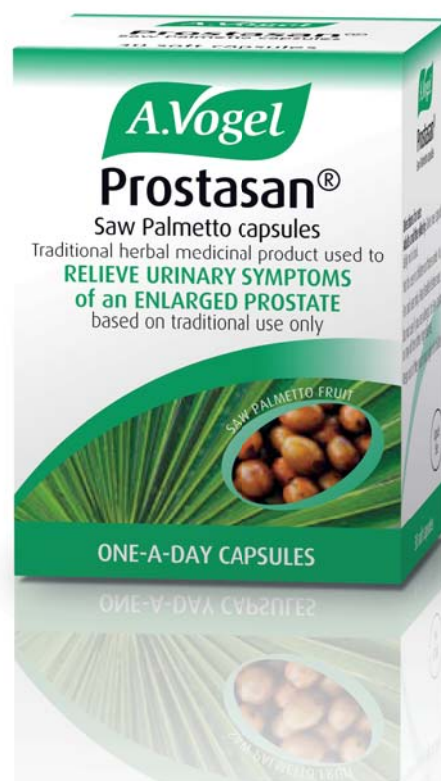
## Prescribing Information

### Prostasan Saw Palmetto capsules

**Active Ingredients:** One capsule contains 320 mg of extract (as soft extract) from Saw Palmetto fruit. **Indications:** Traditional herbal medicinal product used for the relief of lower urinary tract symptoms in men who have a confirmed diagnosis of benign prostatic hypertrophy (BPH) exclusively based on long standing use as a traditional remedy. Prior to treatment other serious conditions should have been ruled out by a doctor. **Dosage and administration:** Adults and the elderly: One capsule daily to be taken with food. Children: Not suitable for children under 18 years of age. **Contraindications:** Hypersensitivity to any of the ingredients. Not suitable for those under 18 years of age. Not suitable during pregnancy or lactation. **Warnings and Precautions:** Do not exceed stated dose. If symptoms worsen consult a healthcare practitioner. If symptoms include haematuria or pyrexia medical advice must be sought immediately. Saw palmetto should be discontinued and the platelet function assessed prior to patients undergoing surgery. Patients taking medication for BPH should consult their doctor before using Prostasan. **Side effects:** Rare: Eructation and gastrointestinal discomfort, allergic reactions. One case report of intraoperative haemorrhage.

**Legal category:** GSL Registration number: THR 13668/0011

**Registration holder:** Bioforce (UK) Ltd, 2 Brewster Place, Irvine, Ayrshire KA11 5DD RRP (ex VAT): £11.17 (30 capsules); £28.54 (90 capsules) Date of Preparation: January 2011



# Patient Information Leaflet (Page 1)

Package Leaflet:  
Information for the User



**Prostasan®**  
Saw Palmetto capsules



## 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 healthcare practitioner.
- You must contact a doctor, pharmacist or 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 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

## Do's and Don'ts for taking this product

### 1. What the product is and what it is used 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.

### 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
- You have blood in your urine
- You have a fever

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.

Please turn over...

## (Page 2)

## Using

### 3. How to take this product

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

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.

#### 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

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.

These are likely to affect less than 1 in every 1,000 people.

- Belching
- Stomach discomfort
- Allergic reactions such as skin rashes

Discontinue use if you find these are troubling you.

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 healthcare practitioner.

### Remember to see your doctor if:

- Your symptoms of urinary discomfort worsen
- You have blood in your urine
- You have a fever

## 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 Prostasan 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 320mg 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.

### What this product looks like and the contents of the pack

Prostasan capsules are soft, oval-shaped and dark brown in colour. Prostasan 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

This leaflet was approved on  
08/2007

### 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](mailto:enquiries@avogel.co.uk)  
Phone: 0845 608 5858

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

Call this number: 0845 608 5858.

# Summary of Product Characteristics

## 1. NAME OF THE MEDICINAL PRODUCT

Prostasan Saw Palmetto Capsules

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 capsule contains 320mg 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.

One capsule contains 6.93 – 8.47 mg sorbitol

For a full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Soft capsule.

It is an oval-shaped, dark brown coloured soft capsule containing a clear, yellow-brown coloured oil.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Traditional herbal medicinal product used for the relief of lower urinary tract symptoms in men who have a confirmed diagnosis of benign prostatic hypertrophy (BPH), based on traditional use only.

Prior to treatment other serious conditions should have been ruled out by a doctor.

### 4.2 Posology and method of administration

Adults and the elderly: One capsule daily to be taken with food.

Children and adolescents less than 18 years old: This product is not indicated in patients less than 18 years.

Hepatic and renal impairment: The safety of Saw palmetto has not been studied in patients with hepatic and/or renal impairment.

### Duration of use

Long term use is possible (see section 4.4, 'Special warnings and precautions for use.')

If symptoms worsen or if no improvement in symptoms is seen after 8 weeks of treatment, consult a doctor or qualified healthcare practitioner.

### 4.3 Contraindications

This product should not be used:

- In patients who have a known hypersensitivity to Saw palmetto or any of the other ingredients used in this product.
- By patients who are under 18 years of age.
- By women who are pregnant or breastfeeding.

### 4.4 Special warnings and precautions for use

Do not exceed stated dose.

This product is intended for use in men who have had benign prostatic hypertrophy already diagnosed by a medical practitioner.

If symptoms worsen or if haematuria or pyrexia occur, medical advice must be sought immediately.

If no improvement in symptoms is seen after 8 weeks of treatment, consult a doctor or qualified healthcare practitioner.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Saw palmetto is unlikely to have an effect on levels of serum prostate specific antigen (PSA).

There has been a case report of intra-operative haemorrhage associated with the use of Saw palmetto. The prolonged bleeding time may have been a result of platelet dysfunction caused by cyclooxygenase inhibition by Saw palmetto. As a precaution Saw palmetto should be discontinued and the platelet function assessed prior to patients undergoing surgery.

Patients taking medication for Benign Prostatic Hypertrophy should consult their doctor before using Prostasan Capsules.

### 4.5 Interaction with other medicinal products and other forms of interaction

Limited interaction studies have identified no clinically important drug interactions.

Saw palmetto does not appear to significantly affect the cytochrome P450 linked enzyme system.

### 4.6 Pregnancy and Lactation

The safety of this product during pregnancy and lactation has not been established, therefore the use of this product during pregnancy and lactation should be avoided.

Fertility: Non-clinical data on constituents of Saw palmetto indicate a potential effect of reduced sperm motility, viability and sperm concentration. The relevance of these findings to humans is not known. (See Section 5.3).

### 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

## 4.8 Undesirable effects

There has been one case report of intraoperative haemorrhage associated with the use of Saw palmetto.

Based on post-marketing data other adverse events that have been reported are:

### Gastrointestinal disorders

- Eructation and gastrointestinal discomfort

### Skin disorders

- Allergic reactions such as rash, pruritis

The frequency is not known.

If other adverse effects not mentioned above occur, a doctor or qualified healthcare practitioner should be consulted.

## 4.9 Overdose

There are no data on human overdose with Saw palmetto. Appropriate symptomatic and supportive treatment should be administered as clinically indicated.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

The active constituents of Saw palmetto have not been established definitively, however the fatty acid and phytosterol (such as  $\Delta$ -sitosterol) components are considered to play a role in its activity.

### 5.2 Pharmacokinetic properties

No definitive pharmacokinetic data are available.

### 5.3 Preclinical safety data

Data on reproductive toxicity are limited. Carcinogenicity studies have not been performed. An Ames test conducted with the extract to investigate genotoxic potential was negative.

$\beta$ -sitosterol (5mg/kg) given subcutaneously for 32 or 48 days had an antifertility effect on male rats by reducing sperm motility, viability and sperm concentration. The relevance of these findings to humans is not known, but it is considered that the low

levels of  $\beta$ -sitosterol in this product are unlikely to have an effect on human fertility.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

Gelatin  
Glycerol  
Sorbitol  
Ferric oxide red  
Ferric oxide black  
Ferric oxide yellow  
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf-Life

Unopened 60 months.

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions. Keep out of the sight and reach of children.

### 6.5 Nature and Contents of Container

Amber glass bottles (Type III glass) with aluminium pilfer proof closure with a polyethylene liner.

Pack sizes: 30 capsules

60 capsules

90 capsules

Not all pack sizes may be marketed.

### 6.6 Instructions for use and handling and disposal

No special requirements.

## 7. REGISTRATION HOLDER

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

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## 8. REGISTRATION NUMBER(S)

THR 13668/0011

## 9. DATE OF FIRST REGISTRATION/ RENEWAL OF REGISTRATION

10/09/2007

## 10. DATE OF REVISION OF THE TEXT

27/09/2012