PhytoCon SABAL FORTE Capsules

THR 34863/0003

UKPAR

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted PhytoCon GmbH & Co KG a Traditional Herbal Registration Certificate for the traditional herbal medicinal product PhytoCon SABAL FORTE Capsules (Traditional Herbal Registration number: THR 34863/0003) on 17 March 2011. PhytoCon SABAL FORTE Capsules are available without prescription and can be bought from pharmacies and other outlets.

PhytoCon SABAL FORTE Capsules is a traditional herbal medicinal product used to relieve the symptoms of urinary tract discomfort in men who have been told that they have an enlarged prostate, based on traditional use only. The active ingredient of PhytoCon SABAL FORTE Capsules comes from Saw palmetto (*Serenoa repens* (Bartram) Small) fruit.

This registration is based exclusively upon the longstanding use of Saw palmetto fruit as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that a product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
PHYTOCON SABAL FORTE CAPSULES

THR 34863/0003

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product PhytoCon SABAL FORTE Capsules (THR 34863/0003) to PhytoCon GmbH & Co KG on 17 March 2011. This product is on the general sales list (GSL).

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. The product is used to relieve the symptoms of urinary tract discomfort in men who have been told that they have an enlarged prostate, also known benign prostatic hypertrophy (BPH), based on traditional use only.

The data supplied by the Applicant demonstrate 30 years of traditional use of Saw palmetto fruit, including at least 15 years of use in the European Community. A satisfactory review of the available safety data on Saw palmetto fruit has also been provided, together with an Expert Safety Report supporting the proposed product.
**PHARMACEUTICAL ASSESSMENT**

**HERBAL SUBSTANCE:**  
Scientific name of the plant: Serenoa repens (Bartram) Small  
Family: Arecaceae  
Synonyms of the herbal substance: Saw palmetto, sabal  
Parts of the plant used: Fruit

**SAW PALMETTO FRUIT**

**Manufacture**
The herbal substance is collected from the wild in the USA (mainly the South-East; in particular Florida and South Carolina) in accordance with Good Agricultural and Collection Practice (GACP) guidelines.

Collection of the Saw palmetto fruits takes place during August and September. The ripe berries are removed by hand and subsequently dried either artificially in special dryers or naturally in open air. The herbal drug is stored in dry and properly aerated storehouses. The dried berries are not fumigated or irradiated.

**Control of Herbal Substance**
An appropriate specification based on the Ph Eur monograph is applied and is acceptable. The specification is supported by the batch data provided.

**Reference Standards or Materials**
Suitable Certificates of Analysis have been provided for the reference substances used.

**Container Closure System**
The herbal substance is stored in an appropriate container. All components of the container closure system comply with Directive 2008/39/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability**
No stability data are provided. A confirmation is given that the herbal substance is tested prior to making the herbal preparation. A shelf-life for the herbal drug based on real time stability data is not necessary because it is a precursor of the active substance, the herbal preparation.

**HERBAL PREPARATION:**  
**SAW PALMETTO FRUIT ETHANOLIC EXTRACT**

**Name:** Saw palmetto ethanolic extract  
**Part of plant used:** Fruit  
**Drug to extract ratio (DER crude):** 9-11: 1 (defined with reference to dried mass)  
**Extraction solvent:** Ethanol 96.0 % v/v
Manufacture
A satisfactory description of the manufacturing process of the herbal preparation has been provided.

The in-process controls are satisfactorily detailed. There are no critical steps identified as the manufacture of the herbal preparation is considered a standard procedure.

Certificates of Analysis for all materials used in the manufacture of the herbal preparation have been provided.

Control of Herbal Preparation
A satisfactory specification with appropriate tests and limits has been provided for the herbal preparation.

Satisfactory analytical procedures are used to control the quality of the herbal preparation. Analytical procedures have been validated, as appropriate.

Certificates of Analysis have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specification.

The proposed specification has been justified satisfactorily.

Reference Standards or Materials
Suitable details have been provided for the reference standards used.

Container Closure System
The herbal preparation is stored in an appropriate container. Confirmation is provided that all components of the container closure system comply with Directive 2008/39/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Stability studies have been carried out under ICH conditions. The results support the proposed retest period of the herbal preparation.

HERBAL PRODUCT: PHYTOCON SABAL FORTE CAPSULES

Description and Composition of the Herbal Product
PhytoCon SABAL FORTE Capsules are oval-shaped, ochre coloured soft capsules containing the herbal preparation (a yellow-brown, oily mass). The capsules shell contains the excipients gelatin polysuccinate, glycerol 85 %, glycerol, purified water, titanium dioxide (E 171) and ferric oxide (E 172).

The choice of excipients is based on experience and compatibility of the chosen excipients with the active substance is confirmed by stability testing. All excipients used comply with their respective European Pharmacopoeial monograph, with the exception of ferric oxide (E 172), which complies with the requirements of Commission Directive 95/45/EC and the USP/NF monographs and is satisfactory.
Representative Certificates of Analysis has been provided for each excipient and are satisfactory.

The glycerol used in this product is of plant origin and, therefore, carries no TSE risk. The gelatin used in this product is derived from pigs. According to the Note for Guidance on Transmissible Spongiform Encephalopathy (TSE) (July 2004), pigs are not a TSE-relevant animal species and, therefore, no TSE certification is needed for the gelatin used in this product.

**Manufacture**
A description and flow-chart of the manufacturing method has been provided. The manufacturing method is a standard procedure.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on product batches and the results are satisfactory.

**Control of Herbal Product**
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

**Reference Standards or Materials**
Suitable details have been provided for the reference standards used.

**Container Closure System**
The capsules are packaged in PVC/aluminium blister packs that are inserted into cardboard folding boxes. Each pack contains either 15, 20, 30, 60, 90 or 100 capsules.

Specifications and certificates are provided from the manufacturers of all container components. Confirmation is provided that all components of the container closure system comply with Directive 2008/39/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability**
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 3 years is appropriate. There are no special storage precautions.

**Assessor’s comments on the Summary of Product Characteristics, label and Patient Information Leaflet**
All product literature is satisfactory.

A package leaflet has been submitted to the MHRA together with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner.
The test shows that the patients/users are able to act upon the information that it contains.

**ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY**

The grant of a Traditional Herbal Registration is acceptable.
NON-CLINICAL ASSESSMENT

NONCLINICAL ASPECTS
The Expert Safety Report submitted by the applicant lists relevant references to published work studying the toxicology of Saw palmetto fruit.

NONCLINICAL OVERVIEW
The applicant has submitted a literature review with this application. An Expert Safety Report was provided, which included reviews of some non-clinical data. The Expert Safety Report was written by a medical doctor with suitable expertise.

The overview submitted in support of this application is satisfactory.

Due to a shortage of published data on Saw palmetto fruit, it is not possible to assess if the safety package for the phytochemical constituents of Saw palmetto fruit is acceptable to the standards of today’s GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and thus the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/05.

An Ames test was carried out on the herbal preparation. No evidence indicating mutagenic potential for Saw palmetto fruit was found.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The SmPC for this product is satisfactory from a non-clinical point of view.

ENVIRONMENTAL RISK ASSESSMENT
An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

CONCLUSION
The information supplied demonstrates the traditional use of Saw palmetto fruit. An adequate literature review of Saw palmetto fruit has been carried out by the applicant and no new non-clinical data was submitted for assessment with this application. Granting of a THR is acceptable.
CLINICAL ASSESSMENT

PROPOSED INDICATION
The applicant has submitted the following therapeutic indication:

“A traditional herbal medicinal product used to relieve the symptoms of urinary tract discomfort in men who have been told that they have an enlarged prostate (benign prostatic hypertrophy or BPH). This is based on traditional use only.

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

The indication is acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has submitted the following:

“For oral use

Adults and the elderly
1 capsule daily to be taken with food.
This medicine is not indicated for use in children and adolescents less than 18 years old (see Section 4.4. Special warnings and precautions for use).

There are no studies on the safety of Saw palmetto in patients with hepatic and/or renal impairment.”

This is acceptable.

EFFICACY
No clinical efficacy data is required for registration of Traditional Herbal Medicinal Products (THMP).

EVIDENCE OF LONG-STANDING USE
Article 16 c 1 (c) requires the Applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the Community.

The Applicant has provided a report describing the traditional use of Saw palmetto within the EU for a period exceeding 30 years. The requirements of the Directive are, therefore, addressed for this aspect.

SAFETY REVIEW
Article 16 c 1 (D) requires the Applicant to provide a bibliographic review of safety data, together with an expert report.

A safety review has been provided and an Expert Report.
The safety review is comprehensive and reveals the main safety issues associated with treatment with Saw palmetto fruit.

PRODUCT LITERATURE
The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product are medically satisfactory.

DISCUSSION
The data supplied by the Applicant demonstrate use for at least 30 years, of which at least 15 years have been in an EU Member State as required for registration under the Traditional Herbal Medicines Product Directive. A satisfactory review of the available safety data relating to Saw palmetto fruit has been provided together with an expert report supporting the registration of the product.

RECOMMENDATIONS
A Traditional Registration may be granted.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

NON-CLINICAL
An Ames test was carried out on the herbal preparation. No evidence indicating mutagenic potential for Saw palmetto fruit was found. No other non-clinical data were submitted with this application. This is satisfactory.

EFFICACY AND SAFETY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products (THMP).

The Applicant has provided a bibliographic review which shows ample evidence for the use of Saw palmetto fruit within the EU for a period exceeding 30 years.

No safety issues have been identified.

The SmPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The risk: benefit balance is acceptable and a Traditional Herbal Registration may be granted.
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<tr>
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<th>STEPS TAKEN FOR ASSESSMENT</th>
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<tr>
<td>1</td>
<td>The MHRA received the Traditional Herbal Registration application on 8 October 2010</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 25 October 2010</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 30 November 2010</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s request, providing further information on the quality dossier on 7 December 2010</td>
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<td>5</td>
<td>Following assessment of the application the MHRA requested further information relating to the clinical dossier on 8 February 2011</td>
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<td>6</td>
<td>The applicant responded to the MHRA’s request, providing further information on the clinical dossier on 16 March 2011</td>
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<td>7</td>
<td>A THR was granted on 17 March 2011</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
PhytoCon SABAL FORTE Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each soft capsule contains 320 mg of extract (as soft extract) from Saw palmetto fruit (Serenoa repens (Bartram) Small) (9-11:1). Extraction solvent: ethanol 96 % (V/V).
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Soft capsule
Oval-shaped, ochre coloured soft capsule containing a yellow-brown, oily mass.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
A traditional herbal medicinal product used to relieve the symptoms of urinary tract discomfort in men who have been told that they have an enlarged prostate (benign prostatic hypertrophy or BPH). This is 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
For oral use

Adults and the elderly
1 capsule daily to be taken with food.
This medicine is not indicated for use in children and adolescents less than 18 years old (see Section 4.4. Special warnings and precautions for use).

There are no studies on the safety of Saw palmetto in patients with hepatic and/or renal impairment.

4.3 Contraindications
Patients with known hypersensitivity to Saw palmetto or any of the excipients of the product.

4.4 Special warnings and precautions for use
Do not exceed the stated dose.
PhytoCon SABAL FORTE Capsules are intended for use in men who have had benign prostatic hypertrophy already diagnosed by a doctor.
The patient should contact a doctor or qualified healthcare practitioner if symptoms worsen or persist.
A doctor should be consulted immediately if symptoms include haematuria or pyrexia.
Serum prostate specific antigen (PSA) levels are probably not affected by Saw palmetto.
An intra-operative haemorrhage associated with the intake of Saw palmetto has been reported. 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 this product.

This product is not recommended for use in children and adolescents less than 18 years old since there is no relevant use in this age group.

4.5 Interaction with other medicinal products and other forms of interaction
Limited interaction studies have identified no clinically important drug interactions. The cytochrome P450 linked enzyme system does not appear to be significantly affected by Saw palmetto.

4.6 Pregnancy and lactation
This product is for use in men only.

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:
- Eructation and gastrointestinal discomfort
- Allergic reactions
The frequency is not known.

If adverse reactions occur, a doctor or pharmacist 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
Not required as per article 16 c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties
Not required as per article 16 c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data
The extract was negative in a test (Ames test) for mutagenicity.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Gelatin polysuccinate
Glycerol
Glycerol 85%
Purified water
Titanium dioxide (E 171)
Ferric oxide (E 172)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
The shelf life is 3 years.

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
The soft capsules are packaged in PVC/Aluminium blister packs.
Folding boxes with blisters containing 15, 20 or 30 soft capsules.

Package sizes: 15, 20, 30, 60, 90, or 100 soft capsules.

Not all pack sizes maybe marketed.

6.6 Special precautions for disposal
No special requirements

7 MARKETING AUTHORISATION HOLDER
PhytoCon GmbH & Co KG
Koblenzer Str. 48-56
56626 Andernach
Germany

8  MARKETING AUTHORISATION NUMBER(S)
THR 34863/0003

9  DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
17/03/2011

10 DATE OF REVISION OF THE TEXT
17/03/2011
PACKAGE LEAFLET: INFORMATION FOR THE USER

PhytoCon SABAL FORTE Capsules

Saw palmetto fruit extract 320 mg

Read all of this leaflet carefully because it contains important information for you. Before using PhytoCon SABAL FORTE Capsules you must have been told by your doctor that you have an enlarged prostate (also known as benign prostatic hypertrophy or BPH). This medicine is available without prescription. You need to take PhytoCon SABAL FORTE Capsules carefully to get the best results from it.

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

In this leaflet:
1. What PhytoCon SABAL FORTE Capsules are and what these are used for
2. Before you take
   PhytoCon SABAL FORTE Capsules
3. How to take
   PhytoCon SABAL FORTE Capsules
4. Possible side-effects
5. How to store
   PhytoCon SABAL FORTE Capsules
6. Further information

1. What PhytoCon SABAL FORTE Capsules are and what these are used for

A traditional herbal medicinal product used to relieve the symptoms of urinary tract discomfort in men who have been told that they have an enlarged prostate (benign prostatic hypertrophy or BPH). This is based on traditional use only.

Used to help relieve symptoms including:
- Feeling like you need to pass urine more often, especially at night
- When you pass urine, the flow of urine is weak or interrupted
- Feeling that you cannot empty your bladder completely

Enlargement of the prostate is also termed benign prostatic hypertrophy (BPH). The prostate gland is only present in men and is located just below the bladder. This gland may be enlarged as men get older and cause urinary discomfort.

2. Before you take
   PhytoCon SABAL FORTE Capsules

Do not take PhytoCon SABAL FORTE Capsules if you:
- are allergic (hypersensitive) to Saw palmetto or any of the other ingredients of PhytoCon SABAL FORTE Capsules (see section 6 for a full list of ingredients)
- are under 18 years of age. This product is not suitable for this age group.

Take special care with
PhytoCon SABAL FORTE Capsules

Before you take PhytoCon SABAL FORTE Capsules a doctor must have told you that you have an enlarged prostate (benign prostatic hypertrophy or BPH). Other serious conditions should have been ruled out by your doctor.

You should see your doctor if your symptoms of urinary discomfort worsen or persist.
Your doctor may have done a blood test for prostatic specific antigen (PSA). It is unlikely that this product will alter your levels of PSA.

Contact your doctor immediately:
- if there is blood in your urine
- if you have a fever

Tell your doctor that you are taking PhytoCon SABAL FORTE Capsules if you are due to undergo surgery.

Taking other medicines
If you are already taking medicines for an enlarged prostate (BPH) consult your doctor before taking PhytoCon SABAL FORTE Capsules as this product may not be suitable for you.

You can use this product with any other medicines.

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. If affected do not drive.
3. How to take
PhytoCon SABAL FORTE Capsules

For oral use only.

Adults and the elderly
1 capsule daily.
Swallow the capsule with food.
Not suitable for use in children and adolescents under 18 years of age.
Do not exceed the stated dose.

If you take more PhytoCon SABAL FORTE Capsules than you should
If you take more than the recommended dose, speak to a doctor and take this leaflet with you. It is not likely to be harmful if you take too much of this product.

If you forget to take
PhytoCon SABAL FORTE Capsules
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

If you stop taking
PhytoCon SABAL FORTE Capsules
The use of this product can be stopped at any time.

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

4. Possible side-effects
Like all medicines, PhytoCon SABAL FORTE Capsules can cause side-effects, although not everybody gets them. They are listed below.

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

Discontinue use if the side effects are troubling.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Remember to see your doctor:
- if your symptoms of urinary discomfort worsen or persists
- if there is blood in your urine
- if you have a fever

5. How to store
PhytoCon SABAL FORTE Capsules
- Keep the capsules out of the reach and sight of children.
- Do not use this product after the expiry date which is stated on the box and the blister pack.
- Do not use the product when you notice a change in the colour of the capsules.
- This product does not require any special storage conditions.

6. Further information

What PhytoCon SABAL FORTE Capsules contain
The active substance is Saw palmetto fruit extract.
Each soft capsule contains 320 mg of extract (as soft extract) from Saw palmetto fruit (Serenoa repens (Bartram) Small) (9-11:1). Extraction solvent: ethanol 96 % (V/V).
The other ingredients are:
Gelatin, polysaccharide, Glycerol, Purified water, Titanium dioxide (E 171), Ferric oxide (E 172)

What PhytoCon SABAL FORTE Capsules look like and contents of the pack
PhytoCon SABAL FORTE Capsules are oval-shaped, ochre coloured soft capsules containing a yellow-brown, oily mass.
Each pack contains 15, 20, 30, 60, 90, or 100 capsules.
Not all pack sizes maybe marketed.

Traditional Registration holder
PhytoCon GmbH & Co KG
Koblenzer Str. 48-58
56626 Andernach
Germany

Manufacturer of the finished product and batch release site:
C.P.M. ContractPharma GmbH & Co. KG
Frühlingstrasse 7
83620 Feldkirchen-Westerham
Germany
Traditional herbal registration number:
THR 34863/0003

If you would like further information about this product, please contact:
PhytoCon GmbH & Co KG
Koblenzer Str. 48-56
56626 Andernach
Germany
Telephone: +49 (0) 2632-924-310

This leaflet was last approved in February 2011.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.yellowcard.gov.uk. Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call freephone 0808 100 3252 (available 10am-2pm Monday to Friday).
The leaflet is available in large print or audio version.
LABELLING

Blister:
Carton:
PhytoCon SABAL FORTE Capsules

Saw palmetto fruit extract 320 mg

A traditional herbal medicinal product used to relieve the symptoms of urinary tract discomfort in men who have been told that they have an enlarged prostate (benign prostatic hyperplasia or BPH). This is based on traditional use only.

Usage to help relieve symptoms including:
- Feeling like you need to pass urine more often, especially at night
- When you pass urine, the flow of urine is weak or interrupted
- Feeling that you cannot empty your bladder completely

Before you take PhytoCon SABAL FORTE Capsules, a doctor must have told you that you have an enlarged prostate (benign prostatic hyperplasia or BPH).

Active ingredient: Each PhytoCon SABAL Capsule contains 320 mg of extract (as soft extract) from Saw palmetto fruit (Serenoa repens (Bartram) Small) (9:1:1). Extraction solvent: Ethanol 96% (v/v).

Dosage: For oral use.
- Adults and the elderly: 1 capsule daily.
- Swallow the capsule with food.
- Not for use in children and adolescents less than 16 years old.

Warning: Do not exceed the stated dose. This product is for use by man only. Do not take PhytoCon SABAL Capsules if you are:
- Allergic (hypersensitive) to Saw palmetto or any of the other ingredients of PhytoCon SABAL FORTE Capsules.
- Under 16 years of age.

Please read the enclosed information leaflet before taking these capsules. If symptoms persist or worsen contact your doctor or qualified healthcare practitioner. Keep the capsules out of sight and reach of children.

THR holder:
PhytoCon GmbH & Co KG
Hoffman Str. 48-56
56526 Andernach
Germany
Telephone: +49 (0) 2632-924-310

Batch Number.
Expiry date:

MHRA PAR; PHYTOCON SABAL FORTE CAPSULES, THR 34863/0003