



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Herbal medicine: summary for the public

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### Saw palmetto fruit

*Serenoa repens* (W. Bartram) Small, fructus

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of saw palmetto fruit. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing saw palmetto fruit.

This summary is not intended to provide practical advice on how to use medicines containing saw palmetto fruit. For practical information about using saw palmetto fruit medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

#### **What is saw palmetto fruit?**

Saw palmetto fruit is the common name for the fruit of the plant *Serenoa repens* (W. Bartram) Small.

Saw palmetto fruit preparations may be obtained by using a technique to extract compounds from plant material by dissolving them in a solvent (hexane or ethanol), which is then partially evaporated to obtain a soft extract.

Herbal medicines containing saw palmetto fruit are usually available in solid forms to be taken by mouth.

#### **What are the HMPC conclusions on its medicinal uses?**

The HMPC concluded that saw palmetto fruit (extracted with hexane) can be used to treat the symptoms of benign prostatic hyperplasia (BPH). BPH is a non-cancerous increase in size of the prostate gland which surrounds the urethra, the tube that carries urine from the bladder out of the body.

The HMPC also concluded that, on the basis of its long-standing use, saw palmetto fruit (extracted with ethanol) can be used for the relief of lower urinary tract symptoms (such as difficulty starting urination or a frequent need to urinate) related to BPH, after serious conditions have been excluded by a doctor.

Saw palmetto fruit should only be used in male adults and the elderly. If symptoms persist during the use of the medicine, a doctor or a qualified healthcare practitioner should be consulted. Detailed



instructions on how to take saw palmetto fruit medicines and who can use them can be found in the package leaflet that comes with the medicine.

## **How does saw palmetto fruit work as a medicine?**

The way saw palmetto fruit acts is not fully known, but from laboratory studies it is thought to work by reducing the action of male sex hormones such as testosterone, which play a role in causing enlargement of the prostate gland in BPH; and it may also have anti-inflammatory effects.

## **What evidence supports the use of saw palmetto fruit medicines?**

The HMPC conclusions on the use of hexane-extracted saw palmetto fruit medicines for the symptomatic treatment of BPH are based on their 'well-established use' in this condition. This means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

In its assessment, the HMPC considered a number of clinical studies with saw palmetto fruit hexane extract some of which showed that it is as effective as finasteride and tamsulosin (other medicines approved to treat BPH) at treating BPH symptoms for periods up to 1 year.

The HMPC conclusions on the use of ethanol-extracted saw palmetto fruit medicines for the relief of lower urinary tract symptoms related to BPH are based on their 'traditional use' in this condition. This means that, although there is insufficient evidence from clinical trials, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU). Moreover, the intended use does not require medical supervision.

In its assessment, the HMPC also considered clinical studies with saw palmetto fruit ethanol extract. Although a possible effect in relief of lower urinary tract symptoms related to BHP was observed, there were shortcomings in the studies such as too few patients and too short a treatment period. Therefore, the HMPC conclusions on the use of saw palmetto medicines are based on their long-standing use.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

## **What are the risks associated with saw palmetto fruit medicines?**

Common side effects (seen between 1 and 10 patients in 100) reported with saw palmetto fruit are abdominal (belly) pain and headache.

Further information on the risks associated with saw palmetto fruit medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: [ema.europa.eu/Find\\_medicine/Herbal\\_medicines\\_for\\_human\\_use](http://ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use).

## **How are saw palmetto fruit medicines approved in the EU?**

Any applications for the licensing of medicines containing saw palmetto fruit have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of saw palmetto fruit medicines in EU Member States should be obtained from the relevant national authorities.

## **Other information about saw palmetto fruit medicines**

Further information on the HMPC assessment of saw palmetto fruit medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use). For more information about treatment with saw palmetto fruit medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.