1. NAME OF THE MEDICINAL PRODUCT

Pollstimol®
Hard capsules
20 mg dry extract of pollen
from rye, timothy and maize
3 mg soft extract of pollen
from rye, timothy and maize

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One hard capsules contains:
20 mg dry extract of dried crude pollen from *Secale cereale* L. (rye), *Phleum pratense* L. (timothy) and *Zea mays* L. (maize) in the ratio 30 : 1.5 : 1, $DER_{genuine}$: (2.7 – 7.5) : 1.
Extraction solvent: water : acetone : sodium laurilsulphate (96 : 4 : 0.022 m/m/m).

3 mg soft extract of dried crude pollen from *Secale cereale* L. (rye), *Phleum pratense* L. (timothy) and *Zea mays* L. (maize) in the ratio 30 : 1.5 : 1, $DER_{genuine}$: (12 – 28) : 1.
Extraction solvent: water : acetone : sodium laurilsulphate (96 : 4 : 0.022 m/m/m)

Excipient with known effect
Lactose
Pollstimol contains less than 1 mmol (23 mg) natrium per dosing unit.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules for oral use
monochrome, beige-yellow

4. CLINICAL PARTICULAR

4.1 Therapeutic indications

- Micturition disorders in the presence of Alken stage I – II or Vahlensieck stage II – III benign prostatic hyperplasia (BPH)
- Chronic non-bacterial prostatitis

4.2 Posology and method of administration

Micturition disorders
The recommended dose is:
2 hard capsules 2 to 3 times per day
Daily dose: 4 to 6 hard capsules

Chronic non-bacterial prostatitis
The recommended dose is:
2 hard capsules 3 times per day
Daily dose: 6 hard capsules

The hard capsules should be taken with sufficient liquid (preferably 1 glass of drinking water) at mealtimes.

The duration of administration is not time-limited and should be not less than 3 months.

4.3 Contraindications

Hypersensitivity to grass pollen or to any of the excipients of Pollstimol.

4.4 Special warnings and precautions for use

This medicinal product improves the symptoms of an enlarged prostate gland only without correcting the enlargement. A doctor should therefore be consulted at regular intervals. Medical advice should be sought particularly if blood appears in the urine or acute urinary retention occurs.

Pollstimol may not be sufficiently effective in the presence of marked outflow obstruction, e. g. caused by urethral stricture, bladder-neck sclerosis or prostatic calcifications.

Therapy with an extract mixture of gras pollen could mask an increase in concentration of serum-PSA. This should be taken into consideration in follow-up controls for PSA in connection with the diagnostic of cancer.

Pollstimol contains lactose, amongst other ingredients. Patients with rare hereditary problems of galactose intolerance, a total Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Children and Adolescents
Children and adolescents should not take Pollstimol.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pollstimol should not be administered to women, especially not to pregnant and breastfeeding ones.

4.7 Effects on ability to drive and use machines

Pollstimol has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Uncommon (≥ 1/1,000 to < 1/100): mild gastrointestinal symptoms
Very rare (< 1/10,000): allergic skin reactions

In the package leaflet, the patient is urged to stop taking the medicinal product and consult a doctor if undesirable effects occur.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de.

4.9 Overdose

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Herbal medicinal product for prostate disorders
ATC code: G04CP

The following pharmacological effects have been demonstrated experimentally:
Antiproliferative effect
In vitro growth inhibition by the water-soluble fraction of the pollen extract mixture of epithelial and fibroblast cells cultured from BPH tissue after stimulation with dihydrotestosterone and oestradiol. Effect on tissue levels of epidermal growth factor (EGF).

Antiinflammatory effect
Inhibition of the release of the proinflammatory cytokines TNF-alpha, IL-6 and IL-2 in the prostate. Dose-dependent *in vitro* inhibition by the acetone-soluble fraction of the pollen extract mixture of cyclo-oxygenase activity (IC_{50} = 0.005 mg/ml) and 5-lipoxygenase activity (IC_{50} = 0.08 mg/ml). This results in decreased leukotriene-induced release of leukotactic substances and reduced prostaglandin synthesis.

Anticongestive effect
As a result of reduced prostaglandin synthesis, reduction in the prostaglandin-induced increase in vascular permeability and consequent oedema.

Spasmolytic effect
In the isolated guinea-pig ileum, a spasmolytic effect was measured from a concentration of 3×10^{-4} g/ml onwards.

5.2 Pharmacokinetic properties

There have been no studies of pharmacokinetics.

5.3 Preclinical safety data

Pharmacological safety studies performed in animals have shown no effect on respiration and the cardiovascular system.
On oral administration of both the water-soluble and acetone-soluble fractions of the pollen extract in male mice and rats, LD_{50} is greater than 6000 mg/kg body weight. With i. p. administration of the extract mixture, LD_{50} is also greater than 6000 mg/kg body weight.
Mutagenicity studies are carried out using an *in vivo* cytogenetic test for chromosome aberrations in rats after oral administration of both the water-soluble and fat-soluble fractions at doses of 5000 mg/kg body weight. Both fractions were tested *in vitro* in cultivated human lymphocytes, in the gene mutation test in V79 cells and in bacterial test systems. In none of these tests was evidence of a mutagenic effect produced.
In sensitisation studies in the guinea-pig skin in the Magnusson-Kligman test, intracutaneous and local administration initially caused no skin irritation; however, subsequent challenge treatment produced marked sensitisation reactions with erythema formation and pustules. The sensitisation rate was 100 %. There is no evidence of sensitisation after oral administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium gluconate (Ph. Eur.)
Calcium hydrogen phosphate dihydrate
Iron oxide hydrate (E 172)
Gelatin
Purified water
Colloidal silicone dioxide
Lactose monohydrate
Magnesium stearate (Ph. Eur.)
Maltodextrin
Microcrystalline cellulose
Sodium dodecylsulfate
Titanium dioxide (E 171)

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in the original package in order to protect from moisture.
Do not store above 25 °C.

6.5 Nature and contents of container

Blister strips inserted in boxes.
Pack sizes:
30, 60 [N 1]; 120 [N 2]; 200 [N 3] and 240 hard capsules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Strathmann GmbH & Co. KG
P.O. Box 610425
22424 Hamburg
Telephone: +49 40/55 90 5-0
Fax: +49 40/55 90 5-100
E-mail: VL.Strathmann.Info@dermapharm.com

8. MARKETING AUTHORISATION NUMBER

36796.00.00

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION

Date of first authorisation: 02.09.1996
Date of last renewal of the authorisation: 28.10.2004

10. DATE OF REVISION OF THE TEXT

May 2021

11. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription. Available only in pharmacies.