SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cernitol Novum film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains:

40 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).

6.6 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, $DER_{geniune}$ (12-28):1.
First extraction solvent: water:acetone:sodium laurilsulphate (96:4:0.022 m/m/m).
Second extraction solvent: acetone.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.
White, oval film-coated tablet, 7x14 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbal medicinal product for the treatment of symptoms in connection with benign prostatic hyperplasia (BPH) e.g. frequent need to urinate and nocturia.

4.2 Posology and method of administration

Adults and elderly men: 1 tablet 3 times daily.
The tablets should be swallowed whole with liquid.

The effect of Cernitol Novum is gradually obtained and it may take up to three months before full effect is achieved. The treatment should be continued to maintain the effect.

There is no relevant indication for use in children, adolescents and women.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- A doctor should be consulted before start of treatment to rule out any underlying, serious illness (e.g. cancer of the prostate or urinary bladder).
- If the symptoms get worse or persist for more than 6 months, a new medical assessment should be performed.

Effects on prostate specific antigen (PSA) and the possibility to detect prostatic cancer
Clinical studies have shown that the concentration of serum PSA may decrease during treatment with Cernitol Novum. There is a risk that a change of the PSA value, which would have been detected in a PSA test, might be masked.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There is no relevant therapeutic indication for women.
Possible effects of Cernitol Novum on male fertility have not been studied.

4.7 Effects on ability to drive and use machines

Cernitol Novum has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Rare cases of nausea, diarrhoea and hypersensitivity such as rash have been reported.

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 the national reporting system listed in Appendix V.

4.9 Overdose

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs used in benign prostatic hypertrophy
ATC code: G04CX

The mechanism of action is not known. In pharmacological studies on animals and cell cultures, pollen extracts have shown anti-inflammatory effects. Furthermore, anti-proliferative properties as well as spasmolytic and spasmogenic effects on smooth muscle have been shown.

5.2 Pharmacokinetic properties

Pharmacokinetic properties have not been studied.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology and toxicity. No mutagenic effects of the pollen extracts have been shown in Ames test (with and without metabolic activation) in testing of mammal cells *in vitro* or in chromosome aberration testing *in vitro* on human lymfocytes and *in vivo* on rats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline
Maltodextrin
Croscarmellose sodium
Silica, colloidal, anhydrous
Poly (vinyl alcohol)
Titanium dioxide (E171)
Silica, hydrophobic colloidal
Macrogol
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Plastic bottle: 150 and 300 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal <and other handling>

No special requirements.

7. MARKETING AUTHORISATION HOLDER

AB Cernelle
Höganäsvägen 365
SE-262 94 Ängelholm
Sweden
E-mail: info@cernelle.se

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

2016-06-15