

SUMMARY OF PRODUCT CHARACTERISTICS

- 1 NAME OF THE MEDICINAL PRODUCT**
SALVIAN Capsules

- 2 QUALITATIVE AND QUANTITATIVE COMPOSITION**
Each capsule contains 300mg of Sage Leaf. (*Salvia officinalis L.*)
For list of excipients see section 6.1.

- 3 PHARMACEUTICAL FORM**
Hard capsules.
Clear size 0 hard capsules.

- 4 CLINICAL PARTICULARS**
 - 4.1 Therapeutic indications**
SALVIAN is a traditional herbal medicinal product used for the relief of excessive sweating associated with the menopause, based on traditional use only.

 - 4.2 Posology and method of administration**
For oral short term use only.
Women experiencing menopausal symptoms:
For the temporary relief of excessive sweating associated with the menopause.
Take 1 capsule per day
swallowed with water.
Duration of use:- 2 weeks.
If symptoms do not improve after 2 weeks during the use of SALVIAN a doctor or a qualified healthcare care practitioner should be consulted.
There is no relevant use in children and adolescents under 18 years of age.

 - 4.3 Contraindications**
Patients with known hypersensitivity to Sage Leaf should not use SALVIAN.

 - 4.4 Special warnings and precautions for use**
There is no relevant use in children and adolescents under 18 years of age.

 - 4.5 Interaction with other medicinal products and other forms of interaction**
None reported
The intake of Sage preparations might influence the effect of medicinal products acting via GABA receptor (e.g. barbiturates, benzodiazepines), even if not seen clinically. Therefore the concomitant use with such medicinal products is not recommended.

- 4.6 Pregnancy and lactation**
The safety of SALVIAN during pregnancy and lactation has not been established. Due to the lack of data, use during pregnancy and lactation is not recommended.
- 4.7 Effects on ability to drive and use machines**
SALVIAN may impair ability to drive and use machines. Patients who are affected should not drive or operate machinery.
- 4.8 Undesirable effects**
None Known.
If adverse reactions occur, a doctor or qualified health care practitioner should be consulted.
- 4.9 Overdose**
Sage Leaf, at a dose in excess of 15g (equivalent to over 50 SALVIAN capsules), has been reported with a sense of heat, tachycardia, vertigo and epileptic form convulsions.

5 PHARMACOLOGICAL PROPERTIES

- 5.1 Pharmacodynamic properties**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
- 5.2 Pharmacokinetic properties**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
- 5.3 Preclinical safety data**
Test on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

- 6.1 List of excipients**
Hypromellose (capsule shell)
- 6.2 Incompatibilities**
Not Applicable.
- 6.3 Shelf life**
3 years.
- 6.4 Special precautions for storage**
Store below 25°C in the original package.

- 6.5 Nature and contents of container**
Duma 110ml HDPE plastic container and tamper evident threaded Duma cap.
SALVIAN pack contains 30 or 60 Capsules.
- 6.6 Special precautions for disposal**
There are no special precautions for disposal of SALVIAN capsules. When the container is empty the label should be removed and the container placed in a recycling bin.
- 7 MARKETING AUTHORISATION HOLDER**
Bio-Health Limited
Culpeper Close
Medway City Estate
Rochester
Kent
ME2 4HU
- 8 MARKETING AUTHORISATION NUMBER(S)**
THR 15817/0005
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
03/09/2009
- 10 DATE OF REVISION OF THE TEXT**
03/09/2009