Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Menoforce Sage tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 51 mg of dry extract from fresh *Salvia officinalis* L. (Sage) leaves, equivalent to 795 – 1370 mg of fresh herb.
Extraction solvent: ethanol 68 % v/v.

Excipients with a known effect:
One tablet contains 10.2 mg sucrose laurate.

For the full list of excipients sees section 6.1.

3 PHARMACEUTICAL FORM

Tablet
It is an olive green to yellow brown, speckled oblong, biconvex, bevelled tablet with a slightly aromatic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the relief of menopausal hot flushes and excessive perspiration, exclusively based on long-standing use.

This product is indicated for use in adults.

4.2 Posology and method of administration

Posology
Adults (18 years and over): 1 tablet daily.

This product is not indicated in patients less than 18 years.

If the symptoms worsen during the use of Menoforce or do not improve after 12 weeks a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Due to a lack of data the safety of this product for long term use has not been established.

Method of Administration
For oral use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to Sage preparations or to any of the excipients listed in section 6.1.
Do not use if pregnant or breast-feeding.

4.4 Special warnings and precautions for use

If the symptoms worsen during the use of Menoforce or do not improve after 12 weeks, consult a qualified healthcare professional e.g. a doctor or pharmacist.

Excessive sweating can be a symptom of a more serious underlying condition.

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

The intake of Sage folium 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 Fertility, pregnancy and lactation

This product should not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

4.8 Undesirable effects

No undesirable effects are reported.

If adverse reactions occur, a doctor or pharmacist should be consulted.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Overdose has been reported after intake of more than 15 g of sage leaves with a sense of heat, tachycardia, vertigo and epileptiform convulsions (seizures).

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

Tests on reproductive toxicity and carcinogenicity have not been performed with Menoforce.

Genotoxicity data available for an extract of Salvia officinalis and for the essential oil of Salvia officinalis in two separate investigations demonstrated negative Ames test results. This is supported by other published data and suggests that the risk of genotoxicity or mutagenicity resulting from the use of Salvia officinalis extracts is negligible.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Sucrose laurate

Croscarmellose sodium
Glycerol distearate
Silica, colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years unopened.
Use within 4 months of opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottles (Type III glass) sealed with coated aluminium foil and closed with pilfer proof screw caps fitted with a polyethylene liner.

Pack sizes: 30 tablets
90 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 REGISTRATION HOLDER

A.Vogel Ireland Limited
Unit 3d
Killeen Road
Dublin 10
D10 TY20
Ireland

8 REGISTRATION NUMBER(S)

TR2309/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd May 2013
Date of last renewal: 2nd May 2018

10 DATE OF REVISION OF THE TEXT

October 2022