

PROFESSIONAL INFORMATION FOR MEDICINES
FOR HUMAN USE



Menoforce

Hot Flush and Night Sweat Remedy

COMPLEMENTARY MEDICINE

Western Herbal Medicine

This unregistered medicine has not been evaluated by the South African Health Product Regulatory Authority for its quality, safety or intended use.

SCHEDULING STATUS:

S0

1 NAME OF THE MEDICINE

**A.VOGEL MENOFORCE
HOT FLUSH AND NIGHT SWEAT REMEDY
(tablets)**

Salvia officinalis L.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Salvia officinalis L. (Sage) 3400 mg

[Fresh leaves, 1:17 extract providing 200 mg dried herb equivalent]

Contains sugar: Sucrose 6,6 mg.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Olive-green to yellowish-brown, slightly dotted, oblong biconvex, bevelled tablets with a slightly aromatic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.Vogel Menoforce Hot Flush and Night Sweat Remedy is a herbal medicine that does not contain oestrogen or have an oestrogen-like action.

It is used for the supportive treatment of menopausal syndrome and associated hot flushes and night sweats, and for the supportive treatment of hyperhidrosis (excessive sweating).

A.Vogel Menoforce Hot Flush and Night Sweat Remedy has the following therapeutic indications in menopausal women:

- To reduce the frequency and intensity of hot flushes.
- To improve sleep quality.
- To improve mental focus (cognitive function) and anxiety.
- To improve fatigue.
- To improve the somato-vegetative symptoms of menopausal syndrome.

4.2 Posology and method of administration

Posology

Adults (18 years and over):

The usual dose is: 1 tablet daily.

The dosage may be increased, on the advice of your healthcare professional to 2 tablets daily (if necessary, for 1 – 2 weeks).

Special populations

Elderly population:

No dosage adjustment is required for this population.

Paediatric population

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

Method of administration

For oral use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to *Salvia officinalis* L. (Sage) preparations or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If the condition worsens or does not improve after 12 weeks, consult a healthcare practitioner.

Sucrose warning:

A.Vogel Menoforce Hot Flush and Night Sweat Remedy contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take A.Vogel Menoforce Hot Flush and Night Sweat Remedy.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in males and females

No information available.

Pregnancy

The safety of this product during pregnancy has not been established. In the absence of sufficient data, the use of A.Vogel Menoforce Hot Flush and Night Sweat Remedy during pregnancy is not recommended.

Breastfeeding

The safety of this product during lactation has not been established. In the absence of sufficient data, the use of A.Vogel Menoforce Hot Flush and Night Sweat Remedy during lactation is not recommended.

Fertility

Fertility studies have not been performed.

4.7 Effects on ability to drive and use machines

A.Vogel Menoforce Hot Flush and Night Sweat Remedy has no effect on mental and/or physical ability to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects

None known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

None known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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In both *in vitro* and *in vivo* models A.Vogel Menoforce Hot Flush and Night Sweat Remedy (a hydroalcoholic, thujone-free extract from freshly harvested *Salvia officinalis* leaves) has demonstrated potent modulation of neuro-receptors (involved with thermoregulation and sweating) as well as serotonin transporters with strong binding affinity to, adrenergic α_{2A} , μ -opioid, muscarinic M_3 and serotonin 5-HT_{1A} receptors with IC₅₀ values of 15 μ g/ml, 20 μ g/ml, 25 μ g/ml and 19 μ g/ml respectively and the highest binding affinity determined to be that from hydroethanolic extracts of the fresh leaves of *Salvia officinalis*.

Both cholinergic and adrenergic nerve terminals are immediately distributed to eccrine sweat glands. The M_3 muscarinic antagonist and adrenergic α_{2A} agonist action of (a hydroalcoholic, thujone-free extract from freshly harvested *Salvia officinalis* leaves) demonstrated in *in vitro* models is suggestive of a peripheral action at the site of sweating and hot flushes since existing muscarinic antagonists such as scopolamine or hyoscyamine are known to inhibit sweating via the M_3 receptor and adrenergic α_{2A} agonistics such as clonidine is known reduces hot flushes.

In addition to peripheral action on sweating and flushing gained from human recombinant receptors, concurring data from native female hypothalamic receptors suggests additional action on central thermoregulation with all affected receptors being associated with thermoregulation with μ -opioid ligands playing a specific role therein, furthermore muscarinic M_3 , α_{2A} adrenergic receptors also being prominently expressed in the thermoregulatory region of the hypothalamus.

In vitro data thus confirms that A.Vogel Menoforce Hot Flush and Night Sweat Remedy demonstrated modulation of neurological pathways involved with thermoregulation and modulation of known therapeutic pathways for menopausal syndrome for the treatment of menopausal hot flushes.

Clinical efficacy and safety:

A four-week randomized, double-blind, placebo controlled trial (n=80) applying A.Vogel Menoforce Hot Flush & Night Sweat Remedy one tablet daily (3400mg ethanolic extract of fresh *Salvia officinalis* leaves) reported tolerability as 'very good' in 100% of cases with no significant change in vital signs or laboratory safety parameters (Na⁺, GOT, GPT, GGT, creatinine, glucose, urine status and sediment).

In an open, multicenter clinical trial on 69 menopausal women applying A.Vogel Menoforce Hot Flush & Night Sweat Remedy one tablet daily (3400mg ethanolic extract of fresh *Salvia officinalis* leaves) for 8 weeks reported tolerability as 'good/very good' by 90% of physicians and patients, there were no significant changes in full blood count parameters, AST, ALT, bilirubin, creatinine, glucose or cholesterol.

5.2 Pharmacokinetic properties

Data on pharmacokinetic effects are not available.

5.3 Preclinical safety data

Tests on reproductive toxicity and carcinogenicity have not been performed with A.Vogel Menoforce Hot Flush and Night Sweat Remedy. Genotoxicity data available for the extract of *Salvia officinalis* used in *Salvia off.* tablets 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.

Bioforce (A.Vogel) *Salvia officinalis* tincture produced by maceration of fresh cut leaves of *Salvia officinalis* in 66% EtOH (1:17) did not demonstrate any oestrogenic activity *in vitro* in terms of the ERLUX assay.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica
Croscarmellose sodium
Glycerol distearate
Microcrystalline cellulose
Sucrose laurate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months unopened.
Use within 4 months of opening.

6.4 Special precautions for storage

No special storage conditions.
Store at or below 25 °C.
Store in the original package/container.

6.5 Nature and contents of container

Amber glass bottles (type III glass), closed with pilfer proof screw caps fitted with a polyethylene liner.
Pack size: 30 tablets

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)

Listing number: 132275

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

April 2020