

SUMMARY OF PRODUCT CHARACTERISTICS

MENOHERB

1 NAME OF THE MEDICINAL PRODUCT

Menoherb[®] Film-coated Tablets
Menolieve Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

6.5 mg of extract (as dry extract) from Black Cohosh rhizome and root (*Cimicifuga racemosa* (L.) Nutt.) (4.5-8.5:1) (equivalent to 29.25-55.25 mg of Black Cohosh).

Extraction solvent: Ethanol 60% v/v.

One film-coated tablet contains 142 mg lactose monohydrate..

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.
White, round, convex curved and with a score mark on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the relief of symptoms of the menopause, such as hot flushes, night sweats, and temporary changes in mood (such as nervous irritability and restlessness) based on traditional use only.

As there is evidence that Black cohosh may have hormone-like actions, it should only be used by women of childbearing potential if contraception is used.

4.2 Posology and method of administration

For oral use only.

For women experiencing menopausal symptoms, take 1 tablet daily. Tablets should be taken at the same time of day if possible (morning or evening) and swallowed whole with plenty of liquid. Do not chew the tablets.

Children and adolescents less than 18 years old

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

Hepatic and renal impairment

The safety of cimicifuga rhizome extract has not been studied in patients with hepatic and/or renal impairment. This product should not be taken by patients who have hepatic impairment or renal impairment.

4.3 Contraindications

Menoherb should not be used:

- In patients under 18 years old.
- Women who are pregnant or breast feeding or in women who could become pregnant (unless contraception is used).
- In patients who have active liver disease or a history of liver damage.
- In patients currently receiving treatment for or has had a history of an estrogen dependent tumour.

4.4 Special warnings and precautions for use

There have been rare cases of hepatic reactions associated with the use of black cohosh. Patients taking Menoherb should be informed to immediately stop the use of the product and consult their doctor if they develop signs and symptoms suggestive of liver dysfunction. (Fatigue, anorexia, yellowing of the skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine).

Advice should be sought from a physician if the patient has a family history of an estrogen dependent tumour.

Oestrogens may only be taken simultaneously with Menoherb[®] under medical supervision, as their effect may be intensified by Black cohosh.

If menstrual disorders occur or menstruation re-appears and if the symptoms are persistent, of unknown origin, or have recently occurred, a doctor should be consulted as this may indicate the presence of other conditions which need to be medically diagnosed.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase

deficiency or glucose-galactose malabsorption should not take this medicine

4.5 Interaction with other medicinal products and other forms of interaction

No studies have been conducted to determine if drug interactions occur with Menoherb.

4.6 Use during pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. Therefore it should be avoided during pregnancy or lactation. Additionally, because of the potential for the product to have hormone-like actions the product should also be avoided by women who could become pregnant unless contraception is used.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very rarely (less than 1 in 1000, but more than 1 in 10000 treated patients), there may be gastrointestinal symptoms (dyspeptic symptoms, diarrhoea), allergic skin reactions (nettle rash, itching of the skin, skin rash), facial oedema and peripheral oedema, and weight gain.

In rare cases, Black cohosh may cause liver reactions (including hepatitis, jaundice and disturbances in liver function tests).

4.9 Overdose

In the event of an overdose, patients are advised to contact a doctor, pharmacist or qualified healthcare professional. A small overdose (up to 4 tablets) is unlikely to cause any symptoms. In the event of a larger overdose (more than 4 tablets), advice should be sought from a doctor. Management of a large overdose should be symptomatic and supportive in nature.

Older herbal texts state that doses of over 5 g unprocessed drug daily may produce symptoms of nausea, vomiting, dizziness, visual and nervous disturbances, reduced pulse rate and increased perspiration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code:G02CP03

ATC Group: G02CP

It is not possible to make conclusive statements about the oestrogen-like stimulating or inhibiting effect of Black cohosh, because the literature data are contradictory.

5.2 Pharmacokinetic properties

No data available

5.3 Preclinical safety data

The preclinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients of the herbal preparation:

Lactose monohydrate

Cellulose powdered

Silica, colloidal anhydrous

Excipients of the tablet:

Silica, colloidal anhydrous

Magnesium stearate

Maize starch

Cellulose, microcrystalline

Sodium starch glycolate (type A)

Excipients of the film-coating:

Hypromellose

Macrogol 4000

Titanium dioxide E 171

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life is 4 years

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Original packages containing 30, 60 or 90 film-coated tablets

Menoherb[®] film-coated tablets are packed in PVC/ PVDC aluminium blisters and inserted into a carton.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Schwabe Pharma (UK) Ltd
Alexander House
Mere Park
Dedmere Road
Marlow
Buckinghamshire
SL7 1PD

8 MARKETING AUTHORISATION NUMBER(S)

THR 23056/0003

9 DATE OF FIRST REGISTRATION

10 DATE OF REVISION OF THE TEXT

March 2007