Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) – 1986
This medicine can be sold without a doctor's prescription

Menopret®

Film-coated tablets

Active ingredients and its quantity per dosage unit:
Each film-coated tablet contains:
Dry extract from Cimicifuga rhizome (Black cohosh) (5-10:1) 2.8 mg
Extraction solvent: ethanol 58% (V/V)

For a list of inactive ingredients and allergens in the medicine – see section 6.
For important information about some of the ingredients of the medicine – see section 2.

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
Take Menopret® according to the instructions in the dosage section of this leaflet. Consult a pharmacist if you need additional information.
Contact a doctor if the symptoms of your illness get worse or if they do not improve after 6 weeks of using the medicine.

1. What is the medicine intended for?

Herbal medicinal product indicated in female adults for the relief of menopausal complaints such as hot flushes and profuse sweating.
Therapeutic group: Black cohosh.

2. Before using the medicine

Do not use the medicine:

- If you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains. The additional ingredients are listed in section 6.
- If you suffer or previously suffered from liver function disturbances.

Special warnings regarding the use of this medicine:
Inform the doctor if:
- Stop taking the medicine and consult a doctor immediately if you develop symptoms suggestive of liver injury (unusual tiredness, loss of appetite, weight loss, yellowing of the skin and/or eyes, severe upper stomach pain with nausea and vomiting, diarrhea or dark urine).
- vaginal bleeding occurs, or if you experience unclear or new symptoms.
- you have been previously treated or if you are currently treated with medicines for breast cancer or other hormone-dependent tumors.
- you are treated with medicines containing estrogen.

Children and adolescents:
Menopret® should not be used in children and adolescents.

Tests and follow-up:
The doctor may refer you for liver function tests.

Drug interactions:
If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
No interactions between Menopret® and other medicines have been reported so far and no studies to identify interactions with other medicines have been performed.

Use of this medicine and food:
There is no information on the effect of food on using this medicine.

Pregnancy and breastfeeding:
Pregnancy: Taking Menopret® during pregnancy is not recommended. As it is still possible for you to become pregnant while experiencing menopausal symptoms, it is recommended to continue using contraception during treatment with this medicine.
Breastfeeding: As it is unknown whether the active ingredient is excreted in human milk, Menopret® should not be used if you are breastfeeding.
If you are pregnant, breastfeeding or think you may be pregnant, consult a doctor before using this medicine.

Driving and using machines: No studies to assess the effects of the medicine on the ability to drive or use machines have been performed.

Important information about some of the ingredients of this medicine: Menopret® contains lactose.
If you have been told by your doctor or if you know that you have an intolerance to some sugars, consult your doctor before taking this medicine.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The usual recommended dosage is:
1 film-coated tablet, twice a day, morning and evening (maximum dosage of 2 film-coated tablets daily).
Do not exceed the recommended dose.

Treatment duration with the medicine:
Consult a doctor or pharmacist if your symptoms do not improve during the treatment with this medicine.
Do not take this medicine for more than 6 months without consulting a doctor.

How to take: The medicine should be swallowed whole with a sufficient amount of drinking liquid. Do not chew or suck the film-coated tablet.

Special populations:
There is no information on the required dosage in cases of impaired renal function.
Patients with a history of liver function disturbances should not take the medicine (see section 2 "Special warnings regarding the use of this medicine" and section 4 "Side effects").

Crushing/halving/chewing: There is no information on crushing. Do not halve the film-coated tablet.

If you have accidentally taken a higher dosage: No cases of overdose due to taking Menopret® have been reported so far. If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. The doctor will decide on the manner of treatment.

If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult a doctor.
Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop the treatment with this medicine without consulting the doctor.

If you stop taking the medicine:
Discontinuing of the treatment is usually harmless.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions on the use of the medicine, consult the doctor or pharmacist.

4. Side effects:

As with any medicine, the use of Menopret® may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
The frequency of the following side effects is not known:

- Liver injury (liver function disturbances, jaundice, hepatitis) is associated with the use of black cohosh containing products
- Skin reaction (hives, rash or itching)
- Swelling of the tissues of the face and the lower limbs (edema)
- Gastrointestinal disorders (dyspepsia, diarrhea)

If a side effect appears, if any of the side effects gets worse or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "reporting drug-related adverse events" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of side effects reporting or by clicking on the following link: https://sideeffects.health.gov.il
Additionally, side effects can be reported to Dr. Samuelov Import and Marketing Ltd. via the following address:
drugsafety@drsamuelov.co.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (Exp. Date) that appears on the carton package or the blister. The expiry date refers to the last day of that month.
Storage conditions: Store at a temperature below 30°C.

6. Additional information:

In addition to the active ingredient, the medicine also contains the following inactive ingredients:
Calcium hydrogen phosphate dihydrate; Lactose monohydrate; Potato starch; Magnesium stearate; Talc; Ammonio methacrylate copolymer, Type A, Dispersion 30% (Eudragit® RL 30D); Titanium dioxide (E 171); Macrogol 6000; Iron oxide yellow (E 172); Iron oxide red (E 172); Sorbic acid; Sodium hydroxide.

What the medicine looks like and contents of the package: Menopret® looks like a terracotta-colored film-coated smooth tablet, round, biconvex and without a score line. The tablet has a diameter of 7.0-7.2 mm.
The film-coated tablets are packed in plastic trays ("blisters"), which are packed in cardboard boxes.

Package size: Menopret® is supplied in cardboard packages containing 4 plastic trays with 15 film-coated tablets each, 60 film-coated tablets in each package.

Registration Holder and Importer: Dr. Samuelov Importing and Marketing Ltd., Company ID 512260944, P.O.B 2486, Ra'anana 4365007. Tel.: 09-7483769, email address: info@drsamuelov.co.il.

Manufacturer: Bionorica SE, 92318 Neumarkt, Germany.

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