Package leaflet: information for the user

Remifemin®

2.5 mg tablets
for use in menopausal women
dry extract from Cimicifuga rhizome

Read all of this leaflet carefully before you start taking this medicine because it contains important information.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor or pharmacist. This include any possible side effects not listed in the leaflet. See section 4.
- You must talk to a doctors if you do not feel better or if you feel worse after 4 to 6 weeks.

What is in this leaflet

1. What Remifemin® is and what it is used for

Remifemin® is an herbal medicine used to relieve menopausal complaints.

Remifemin® is used for relief of psychological and neurovegetative complaints due to menopause such as hot flushes, sweating, and sleeping disorders.

2. What you need to know before you take Remifemin®

Do not take Remifemin®
if you are hypersensitive (allergic) to Cimicifuga rhizome (Black Cohosh rootstock) or any of the other ingredients of this medicine listed in section 6.

Warnings and precautions
Be careful when using Remifemin®:
- if you experience any unusual menstrual problems or your menstruation reappears.
  Also, if unclear symptoms persist or new symptoms appear, you should consult a doctor. In these cases, there may be an illness that needs to be investigated by a doctor.
- if you take estrogens at the same time. This should only take place under medical supervision. Remifemin® may intensify the effect of the estrogens. Consult your doctor.
- if you already have liver injury. Then Remifemin® should only be taken after consultation with your doctor.

- if symptoms suggesting a liver injury (yellowing of the skin or eyes, dark urine, upper stomach pain, nausea, loss of appetite, tiredness) occur. You should immediately stop taking Remifemin® and consult a doctor.
- if you have been treated or you are undergoing treatment for breast cancer or other hormone-dependent tumors, you should not use Remifemin® without medical advice.
- if the symptoms worsen during the use of Remifemin®, you should consult a doctor or a pharmacist.

Taking Remifemin® with other medicines:
There are no known interactions.
Please, however, tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines.

Pregnancy and breast-feeding:
Safety during pregnancy and breast-feeding cannot be assessed due to insufficient data. Therefore, the use during pregnancy and breast-feeding is not recommended. Women of childbearing potential should consider an effective method of contraception during treatment.

Driving and using machines:
No studies have been conducted on the ability to drive and use machines. No negative effects are known.

Remifemin® contains milk sugar (lactose).
Therefore, contact your doctor before taking Remifemin® if you know that you have an intolerance of certain sugars.

3. How to take Remifemin®

Always take this medicine exactly as described in this package leaflet or as your doctor or pharmacist have told you. Please check with your doctor or pharmacist if you are not sure.

The recommended dose is:
Twice daily (morning and evening) 1 tablet to be taken unchewed with a small amount of liquid. (Do not suck on the tablet.)
The tablets do not need to be taken with a meal.

The score-line is not to be used to split the tablet.

Due to the therapeutic indication, the use in children, adolescents, and men is not intended.

There is insufficient data available for specific dosage recommendations for impaired kidney/liver function.

Duration of treatment:
Remifemin® does not reveal its effect immediately. The first therapeutic effects are apparent after two weeks of treatment. It is advisable to take Remifemin® for several months but not longer than six months without medical advice.

If you take more Remifemin® than you should:
An overdose of Remifemin® could worsen the possible side effects. If this happens, you should stop taking the medicine and consult a doctor. If none of these side effects occur, continue taking the usual dose at the usual time.

If you forget to take Remifemin®:
Do not take a double dose to make up for a forgotten tablet; instead, continue taking at the usual time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Remifemin® can cause side effects, although not everybody gets them.

Potential side effects:

rare: may affect up to 1 in 1,000 people	- gastrointestinal disorders (upper abdominal symptoms, diarrhea) - allergic skin reactions (hives, itching, skin rash) - facial swelling or peripheral swelling (facial or peripheral edema) - weight gain
not known: frequency cannot be estimated for the available data	- cases of liver injury during the use of medicines containing Cimicifuga - increase in liver enzymes (transaminases)

In these cases, you should stop taking the medicine and consult your doctor.

Reporting side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via *the national reporting system*. By reporting side effects, you can help to provide more information on the safety of this medicine.

5. How to store Remifemin®

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the side flap of this pack. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

6. Contents of the package and other information

What Remifemin® contains:

The active substance is:
1 tablet contains
2.5 mg dry extract from Cimicifuga rhizome (6 - 11 : 1)
extraction solvent: propan-2-ol (40% V/V)

The other ingredients are:
cellulose powder, lactose monohydrate, potato starch, magnesium stearate

What Remifemin® looks like and contents of the pack:

Round, light beige-colored tablets with a score-line that is not to be used to split the tablet.

Remifemin® is available in packs containing 60 (N2), 100 (N3) and 200 tablets. [Hospital packs with 1000 tablets (10x 100 tablets)].
Not all pack sizes may be marketed.

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This leaflet was last revised in March 2019.