

Package leaflet: information for the user

Remifemin®

tablets, dry extract of Cimicifuga rhizome

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take **Remifemin®** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 4 to 6 weeks.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **Remifemin®** is and what it is used for
2. Before you take **Remifemin®**
3. How to take **Remifemin®**
4. Possible side effects
5. How to store **Remifemin®**
6. Further information

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

Remifemin® is a herbal medicine to relieve menopausal complaints (climacteric).

Remifemin® is used to relieve the psychological and neurovegetative complaints caused by the menopause, such as hot flushes, sweating and sleep disturbances.

2. Before you take **Remifemin®**

Do not take **Remifemin®**

if you are hypersensitive (allergic) to Cimicifugae rhizome (Black Cohosh rootstock) or any of the other ingredients of **Remifemin®**.

Take special care with **Remifemin®**

- if you experience any menstrual problems or your menstruation reappears. Also if unclear symptoms persist or new symptoms appear you should consult a doctor. This is because they may be evidence of illnesses that require investigation by a doctor.
- if you take oestrogens concurrently, it should only occur under medical supervision. **Remifemin®** may intensify the effect of the oestrogens. Consult your doctor.
- if you already have liver injury. Then **Remifemin®** should only be taken after consultation with your doctor.
- if signs and symptoms suggestive a liver injury (yellowing of the skin or eyes, dark urine, upper stomach pain, nausea, loss of appetite, tiredness) occur. You should stop taking **Remifemin®** immediately and consult your doctor.

Taking **Remifemin® with other medicines:**

There are no known interactions.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding:

There are no adequate data on the use of **Remifemin**[®] during pregnancy and breast-feeding. **Remifemin**[®] should therefore not be taken during pregnancy and breast-feeding.

Driving and using machines:

There are no special precautions necessary.

Important information about some of the ingredients of **Remifemin[®]:**

This medicine contains lactose. Therefore do not take **Remifemin**[®] until you have consulted your doctor if you know that you suffer from a sugar intolerance.

3. How to take **Remifemin[®]**

Always take **Remifemin**[®] exactly as directed in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed, the usual dose is:

Twice daily (morning and evening) 1 tablet to be taken unchewed with a little liquid (**do not suck**). You can take the tablets independently from the meals.

Method of administration:

Remifemin[®] is for oral use.

Duration of use:

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 three months without medical advice. Please take note of the information under "Before you take **Remifemin**[®]".

Please consult your doctor or pharmacist if you have the impression that the effect of **Remifemin**[®] is too strong or too weak.

If you take more **Remifemin[®] than you should:**

In the event of overdose of **Remifemin**[®], the listed side effects may worsen. If this happens, you should stop taking the medicine and consult a doctor.

If you forget to take **Remifemin[®]:**

Do not take a double dose to make up for a forgotten tablet, but continue taking the medicine as directed in this package leaflet or as prescribed by your doctor.

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

4. Possible side effects

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

Assessment of side effects is based on the following frequency rates:

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| very common: more than 1 in 10 patients treated |
| common: less than 1 in 10, but more than 1 in 100 patients |
| uncommon: less than 1 in 100, but more than 1 in 1000 patients |

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|---|
| rare: less than 1 in 1000, but more than 1 in 10,000 patients |
| very rare: less than 1 in 10,000 patients, or unknown |

Possible side effects

| | |
|---|--|
| rare: less than 1 in 1000, but more than 1 in 10,000 patients | - gastrointestinal disorders (upper abdominal disorders, diarrhoea), - allergic skin reactions (urticaria, pruritis, skin rash) - face swelling or peripheral swelling - increase in liver enzymes (transaminases) - weight gain |
| very rare: less than 1 in 10,000 patients, or unknown | - reports of liver injury during the use of medicines containing <i>Cimicifuga</i> rhizome. No definite causal connection with these medicines has been proved at present. |

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store *Remifemin*[®]

Keep out of the reach and sight 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.

Do not store above 30°C.

6. Further information

What *Remifemin*[®] contains:

The active substance is:

1 tablet contains
dry extract of *Cimicifuga* rhizome (6 - 11:1) 2.5 mg
extraction agent: 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-coloured tablets

Remifemin[®] is available in packs containing 60, 100 and 200 tablets (hospital pack containing 1000 tablets (10 times 100 tabs.).

Marketing authorisation holder and manufacturer

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