

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.

Remifemin[®] is used for relief of psychic and neurovegetative complaints due to the climacteric such as hot flushes, sweating and sleeping disorders.

2. 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 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 there 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 then stop taking Remifemin[®] immediately and consult your doctor.
- if you have been treated or you are undergoing treatment for breast cancer or other hormone-dependent tumours, 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 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 other ingredients of Remifemin®:

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Remifemin®.

3. How to take Remifemin®

Always take Remifemin® exactly as directed in this package leaflet. Please 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 six 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.

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:

very common:	more than 1 per 10 treated patients
common:	less than 1 per 10, but more than 1 per 100 treated patients

uncommon:	less than 1 per 100, but more than 1 per 1,000 treated patients
rare:	less than 1 per 1,000, but more than 1 per 10,000 treated patients
very rare:	less than 1 per 10,000 treated patients, or unknown

Possible side effects:

rare: less than 1 per 1,000, but more than 1 per 10,000 treated patients	<ul style="list-style-type: none"> - gastrointestinal disorders (upper abdominal disorders, diarrhoea), - allergic skin reactions (urticaria, pruritus, skin rash) - face swelling or peripheral swelling - increase in liver enzymes (transaminases) - weight gain
very rare: less than 1 per 10,000 treated patients, or unknown	<ul style="list-style-type: none"> - reports of liver injury during the use of medicines containing Cimicifuga rhizome. No definite causal relationship 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.

This medicinal product does not require any special storage conditions.

6. Further information

What Remifemin® contains:

The active substance is:

- 1 tablet contains
- 2.5 mg dry extract of Cimicifuga rhizome (6 - 11:1)
- 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.

Marketing authorisation holder and manufacturer

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