

Package leaflet: information for the user

Remifemin® plus

Coated tablets, dry extract of St. John's Wort and 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® plus* 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® plus* is and what it is used for
2. Before you take *Remifemin® plus*
3. How to take *Remifemin® plus*
4. Possible side effects
5. How to store *Remifemin® plus*
6. Further information

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

Remifemin® plus is a herbal medicine to relieve menopausal complaints.

Remifemin® plus is used to relieve the menopausal complaints (climacteric) such as: hot flushes, sweating, depressive moods and psychovegetative disturbances such as dejection, inner tension, irritability, lack of concentration, insomnia, anxiety and/or nervous restlessness, premenstrual psychovegetative disorders.

2. Before you take *Remifemin® plus*

Do not take *Remifemin® plus*

- if you are concomitantly treated with another medicine containing one of the following medicinal agents or a medicinal agent of one of the following substance groups:

Medicine for suppression of transplant rejections

- ciclosporin
- tacrolimus for internal use
- sirolimus

Medicinal drugs for treatment of HIV-infections or AIDS

- proteinase inhibitors such as indinavir
- non-nucleosid-reverse-transcriptase-inhibitors such as nevirapin

Cytostatics such as

- imatinib
- irinotecan

with the exception of monoclonal antibodies

- if you are hypersensitive to Cimicifugae rhizome or St. John's Wort or any of the other ingredients of *Remifemin® plus*
- if you know about existing photohypersensitivity of the skin.

Take special care with *Remifemin® plus*:

Medicinal products like *Remifemin® plus* containing St. John's Wort (*Hypericum*) may interact with other medicinal agents: active substances of *Hypericum* may accelerate the excretion of other medicinal agents and thus reduce the efficacy of these other substances.

As far as a concomitant use of *Remifemin® plus* with other medicinal products is regarded as necessary, your doctor has to consider the possible interactions: Reduction of effects of digoxin, verapamil, simvastatin, midazolam, anticoagulants (phenprocoumon, warfarin).

Women taking oral contraceptives should be advised of the possibility of interaction causing intermenstrual bleeding and of the need for additional contraceptive measures, as the reliability of the contraceptive can possibly be reduced.

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 this should be done only under medical supervision. *Remifemin® plus* may intensify the effect of the oestrogens. Consult your doctor.

If you already have liver injury. Then *Remifemin® plus* should only be taken after consultation with your doctor.

If signs and symptoms suggesting 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® plus* immediately and consult a doctor.

Taking *Remifemin® plus* with other medicines:

Remifemin® plus may interact with various other medicines in such a way that the concentration of these substances in the blood is reduced and thus possibly their efficacy, too. The following medicinal agents belong to these substances:

- anticoagulants (phenprocoumon, warfarin)
- digoxin
- verapamil
- simvastatin
- midazolam
- hormonal oral contraceptives (occurrence of intermenstrual bleedings)
- different agents against depression such as amitriptyline and nortriptyline.

In case of simultaneous intake of certain active agents for treatment of depression (trazodone, paroxetine, sertraline) adverse reactions (such as e.g. nausea, vomiting, anxiety, restlessness, confusion) may increasingly occur in single cases.

If given simultaneously with other medicines which increase skin photosensitivity, an increase in the phototoxic effects (see section on "undesirable effects") is possible.

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® plus* during pregnancy and breast-feeding. *Remifemin® plus* 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® plus*:

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 this medicinal product.

3. **How to take *Remifemin® plus***

Always take *Remifemin® plus* 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:

Take 1 coated tablet twice a day, if necessary 2 coated tablets twice a day. Take the coated tablets in the morning and evening unchewed with some liquid. You can take the coated tablets independently from the meals.

Method of administration:

Remifemin® plus is for oral use.

Duration of use:

As the results of treatment improve further on prolonged administration, *Remifemin® plus* should be taken over a longer period. In order to avoid overlooking of other illnesses, a doctor should be consulted after 6 months.

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

If you take more *Remifemin® plus* than you should:

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

If you forget to take *Remifemin® plus*:

Do not take a double dose to make up for a forgotten tablet.

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

4. **Possible side effects**

Like all medicines, *Remifemin® plus* 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 patients treated
common:	less than 1 per 10, but more than 1 per 100 patients
uncommon:	less than 1 per 100, but more than 1 per 1,000 patients
rare:	less than 1 per 1,000, but more than 1 per 10,000 patients
very rare:	less than 1 in 10,000 patients, or unknown

Possible side effects:

rare: 1 to 10 in 10,000 patients treated	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
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<p>very rare: less than 1 in 10,000 treated patients, or unknown</p>	<ul style="list-style-type: none"> - tiredness or agitation - particularly in light-skinned persons, due to the increased sensitivity of the skin (photosensitisation): sunburn-like reactions in parts of the skin which have been exposed to strong light (sun, solarium). - reports of liver injury during the use of medicines containing Cimicifuga rhizome. No definite causal connection with these medicines has been proved at present.
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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® plus*

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 25°C!

6. Further information

What *Remifemin® plus* contains:

The active substances are:

1 coated tablet contains:

Hyperici herb. extr. sicc. (dry extract of St. John's Wort) corresponding to total hypericin (standard.) = 0.25 mg

Cimicifugae rhiz. extr. sicc. (dry extract of Black Cohosh) corresponding to triterpene glycosides calculated as 27-Deoxyactein (standard.) = 1 mg

The other ingredients are:

Microcrystalline cellulose, ironoxid E 172, glyceryl behenate, glyceryl alconate, colloidal anhydrous silica, indigotin E 132, potato starch, lactose, macrogol mw=6000, magnesium stearate, methylhydroxypropyl cellulose, talc

What *Remifemin® plus* looks like and contents of the pack:

Round-convex, dark-green- coloured coated tablets

Remifemin® plus is available in packs containing 60, 100 and 120 coated tablets.

Marketing authorisation holder and manufacturer

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