Patient Information Leaflet: Information for the user

Remifemin® plus St. John's wort film-coated tablets

for use in climacteric women
dry extract of St. John's Wort, dry extract of Cimicifuga rhizome

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

Always take this medicinal product exactly as described in this package leaflet or exactly as directed by your doctor or pharmacist.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist, if you need more information or advice.
- If you notice any side effects, contact your doctor or pharmacist. This also refers to side effects not listed in this package leaflet; see section 4.
- If you do not feel better or even worse after 4 to 6 weeks, you must contact a doctor.

What is written in this package leaflet:

1. What is Remifemin® plus St. John's wort and what is it used for?

Remifemin® plus St. John's wort is a herbal medicinal product for relief of climacteric complaints.

Remifemin® plus St. John's wort is used during the climacteric for relief of hot flushes and perfused sweating, if these symptoms are accompanied by additional psychic climacteric complaints such as e.g. depressive moods, nervousness and irritability.

2. What should you consider before taking Remifemin® plus St. John's wort?

2.1 Remifemin® plus St. John's wort must not be used,

if you are hypersensitive (allergic) to Cimicifuga rhizome, St. John's Wort, soy, peanut or one of the other ingredients of Remifemin® plus St. John's wort listed in section 6.

Do not use Remifemin® plus St. John's wort, if you are concurrently treated with another medicine which contains one of the following active substances or an active substance of one of the following substance groups:

a) medicinal products for suppression of rejection reactions against transplants
- ciclosporin
- tacrolimus for internal use

b) medicinal products for treatment of HIV-infections or Aids

- proteinase-inhibitors such as indinavir and fosamprenavir

c) cytostatics such as
- irinotecan

d) medicinal products for inhibition of blood coagulation
- warfarin

2.2 Take special care with Remifemin® plus St. John's wort,

- if you already have liver injury (see section 4.8 „Side effects"). Then you should take Remifemin® plus St. John's wort only after consultation with your doctor.
- if signs and symptoms suggestive of liver injury (yellowing of the skin or eyes, dark urine, severe upper stomach pain, nausea, loss of appetite, tiredness) occur. Then you should stop taking Remifemin® plus St. John's wort immediately and consult a doctor.
- if you have been treated or you are undergoing treatment for breast cancer or other hormone-dependent tumours, in these cases you should not take Remifemin® plus St. John's wort without medical advice.
- if you take oestrogen-containing medicines. Then you should not take Remifemin® plus St. John's wort without medical advice.
- if you experience any menstrual disorders or your menstruation reappears after discontinuation or if unclear symptoms persist or other complaints newly appear, you should consult a doctor. This is because they may be evidence of illnesses that require investigation by a doctor.

Medicinal products such as Remifemin® plus St. John's wort that contain components of St. John's wort (Hypericum) may interact with other medicinal products: active substances of Hypericum may accelerate the excretion of other active substances and, thus, reduce the efficacy of these other substances. Active ingredients of Hypericum may also increase the concentration of a so-called 'messenger' (the serotonin) in the brain, so that this substance may under certain conditions cause undesired effects, especially in combination with other medicines effective against depression (see section 2.3 "Taking Remifemin® plus St. John's wort with other medicines").
In the event that you already take Remifemin® plus St. John's wort, you should inform your doctor about this, if he/she prescribes another medicine for you or if you additionally want to take another medicine. In specific cases it has to be considered to discontinue the treatment with Remifemin® plus St. John's wort.

- Women who use hormonal contraceptive measures (e.g. "the pill") and concomitantly Remifemin® plus St. John's wort may experience intermenstrual bleeding resulting from an interaction (see section 2.3). The safety of the hormonal contraceptive may be decreased so that additional contraceptive measures should be taken.

- During the use of Remifemin® plus St. John's wort you should avoid excessive insolation and the visit of solaria.
- At least 1 – 2 weeks before planned surgery with general or partial anaesthesia you should talk to your doctor in order to identify possible interactions with the used preparations. In this case Remifemin® plus St. John's wort should be stopped at least one week prior to the surgery.

2.3 Taking Remifemin® plus St. John's wort with other medicines

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

Due to possible interactions do not take Remifemin® plus St. John's wort together with the medicinal products already listed under section 2.1.

Remifemin® plus St. John's wort can interact with numerous other medicines in such a way that they decrease the concentration of these substances in the blood and, thus, their efficacy may be reduced. The following agents belong to these substances:

- digoxin
- simvastatin
- fexofenadine
- benzodiazepines
- methadone
- *hormonal contraceptives (e.g. "the pill"),* and in addition
- *different agents against depressions* such as
  - amitriptyline

Remifemin® plus St. John's wort may enhance serotonergic effects (such as nausea, vomiting, anxiety, restlessness, disorientation), if it is combined with the following active substances:

Other antidepressants of the SRI- or SSRI-type such as:
- paroxetine
- sertraline

as well as
- buspirone and
- triptanes

If given concomitantly with other medicinal products which increase the photosensitivity of the skin, an increase of the phototoxic effects is possible (see section 4 „side effects").

2.4 Pregnancy and breastfeeding:

Before you take any medicinal product ask your doctor or pharmacist for advice.

There are no adequate data for the assessment of the safety during pregnancy and breastfeeding. Due to insufficient data the use during pregnancy and breastfeeding is not recommended. During the treatment women of child-bearing age should consider an effective non-hormonal contraception method (see section 2.1).

2.5 Effects on ability to drive and use machines:

No studies have been performed on the ability to drive and use machines.

2.6 Important information on certain other ingredients of Remifemin® plus St. John's wort:

This medicinal product contains 163 mg lactose (milk sugar) per film-coated tablet. Therefore, please take Remifemin® plus St. John's wort only after consultation with your doctor, if you know that you suffer from an intolerance to certain sugars.

3. How to take Remifemin® plus St. John's wort

Always take Remifemin® plus St. John's wort as directed in this package leaflet. Please ask your doctor or pharmacist, if you are not quite sure.

3.1 If not otherwise prescribed by the doctor, the usual dosage is:
At the beginning of the treatment (during the first 8 weeks) twice daily 2 film-coated tablets, thereafter twice daily 1 film-coated tablet.

Due to the indication, a use in children, adolescents and males is not envisaged.

There are no sufficient data for specific dosage recommendations in case of impaired renal/liver function.

3.2 Method of administration:
Take the film-coated tablets unchewed with liquid in the morning and in the evening. You can take the film-coated tablets independently from the meals.

3.3 Duration of use:
Remifemin® plus St. John's wort do not reveal its effects immediately. An improvement of the complaints can usually be seen after 2 to 4 weeks. It is recommended to take Remifemin® plus St. John's wort during several months, but without medical advice not longer than 6 months. If the psychic climacteric complaints remain unchanged after 6 weeks, medical advice should be sought, too.

Please talk to your doctor or pharmacist, if you have the impression that the effects of Remifemin® plus St. John's wort are too strong or too weak.

3.4 If you take more Remifemin® plus St. John's wort than you should:
Acute intoxications by St. John's Wort/Cimicifuga preparations in humans have not been reported to far. In case of considerable overdose the patients should be protected from sunlight and UV-radiation, respectively, for the duration of 1 to 2 weeks. The listed side effects may increasingly occur. If you have taken a considerable overdose of this medicinal product, you should consult a doctor.

3.5 If you forget to take Remifemin® plus St. John's wort:
Do not take the double dose, but continue the intake at the usual time.

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

4. Which side effects are possible?
Like all medicines Remifemin® plus St. John's wort can cause side effects, although not everybody gets them.

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

very common:	may concern more than 1 of 10 persons treated
common:	may concern 1 of 10 persons treated
uncommon:	may concern 1 of 100 persons treated
rare:	may concern 1 of 1,000 persons treated
very rare:	may concern 1 of 10,000 persons treated
not known:	frequency cannot be estimated from the available data

Possible side effects:

rare:	- gastro-intestinal complaints (upper stomach pain, diarrhoea) - allergic reactions of the skin (urticaria, pruritus, skin rash)

very rare:	- (3-*sn*-phosphatidyl)choline (lecithin from soy bean) may very rarely cause allergic reactions.
frequency not known:	- cases of liver injury (including hepatitis, jaundice as well as disorders of liver function tests) during the use of Cimicifuga-containing medicines - increase in liver values (transaminases) - swelling in the face or at the extremities (facial or peripheral oedema) - weight gain - sunburn-like reactions of the skin mainly in light-skinned persons after strong UV-radiation without sufficient sun protection - tiredness or restlessness

In these cases you should stop taking the medicinal product and consult your doctor.

Reporting of side effects:
If you notice side effects, please contact your doctor or pharmacist. This refers also to side effects not listed in this package leaflet.
You may also report side effects directly to … (*the national reporting system*)
Your reporting of side effects may contribute to making available more information on the safety of this medicinal product.

5. How to store Remifemin® plus St. John's wort

Keep out of the reach and sight of children.

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

Do not store above 25°C!

6. Contents of the package and further information

What Remifemin® plus St. John's wort contain:

The active substances are:
1 film-coated tablet contains
70 mg dry extract of St. John's Wort (3.5–6 : 1), extraction agent: ethanol 60 % (v/v) and
3.75 mg dry extract of Cimicifuga rhizome (6–11 : 1), extraction agent: propan-2-ol 40% (v/v).

The other ingredients are:
microcrystalline cellulose, glyceryl dibehenate, colloidal anhydrous silica, lactose monohydrate, lactose, poly(vinylalcohol), (3-*sn*-phosphatidyl)choline (soybean), xanthan gum, talc, colourants: titanium dioxide (E 171), iron(III)-hydroxide oxide E 172, indigo carmine E 132.

How Remifemin® plus St. John's wort looks like and contents of the pack:

Green, silk-mat, round film-coated tablets

Remifemin® plus St. John's wort is available in packs with 60, 100, 120 and 180 film-coated tablets.

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