Information and directions for use: User information

remifemin® plus Johanniskraut

Film-coated tablets

For use by menopausal women, St. John's wort dry extract, Cimicafuga rootstock dry extract

Please read the entire package leaflet carefully before you begin to take this medicinal product; it contains important information.

Always take this medicinal product exactly as described in this package leaflet or exactly as instructed by your physician or pharmacist.

- Keep the package leaflet. You may wish to refer to it later.
- If you require further information or advice, ask your pharmacist.
- Contact your physician or pharmacist if you notice side effects. This also applies to side effects that are not listed in this package leaflet; see Section 4.
- Contact your physician if you do not feel better or possibly worse after 4 to 6 weeks.

Information that is contained 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 an herbal medicinal product that alleviates the pain of menopause.
Remifemin® plus St. John's wort is used during menopause to alleviate hot flashes and profuse sweating when these symptoms are accompanied by additional, psychological menopausal symptoms such as distressful states, nervousness and irritability.

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

2.1 Remifemin® plus St. John's wort should not be taken

- if you are hypersensitive (allergic) to Cimicifuga rootstock, St. John's wort, soya, peanuts or to the other ingredients of Remifemin ® plus St. John's wort listed in Section 6.
- Do not use Remifemin® plus St. John's wort you are taking another medicinal product at the same time that contains the following pharmaceutical ingredients or a pharmaceutical ingredient made of the following substance groups:
  - *a) Medicinal product that inhibits rejection reactions to transplants*
    - Cyclosporine
    - Tacrolimus used internally
  - *b) Medicinal product to treat HIV infections or AIDS*
    - Proteinase inhibitors such as indinavir or fosamprenavir
  - *c) Cytostatics such as* irinotecan
  - *d) Medicinal product that inhibits blood clotting*
    - Warfarin

2.2 Particular caution is required when taking Remifemin® plus St. John's wort

- if your liver has previously been damaged (see Section 4 "Side effects"). In that case, Remifemin® plus St. John's wort should be taken only after consultation with a physician.
- if signs of liver damage arise (yellow skin- or eye colour, dark urine, intense upper abdominal pain, nausea, loss of appetite, fatigue). You should then immediately stop taking Remifemin® plus St. John's wort and see a physician.
- if you are or were being treated for breast cancer or another hormone-dependent tumour . In such cases you should not take Remifemin® plus St. John's wort without consulting a physician.
- if you are taking oestrogen-containing medicines. Then you should not take Remifemin® plus St. John's wort without consulting your physician.
- if your menstruation is disrupted or menstruation occurs again after a pause or if you suffer ill-defined pain or if other symptoms newly arise. You should see a physician in that case. These cases may involve diseases that should be clarified by a physician.

Pharmaceutical products that, as with Remifemin® plus St. John's wort, contain components made of St. John's wort (Hypericum) can interact with other pharmaceutical substances: Ingredients with hypericum can accelerate the excretion of other pharmaceutical substances and thus reduce the effectiveness of these other substances. Ingredients made of Hypericum, however, can also increase the concentration of a so-called "messenger substance" (serotonin) in the brain, so that this substance can lead to undesirable effects in certain cases, in particular in combination with other anti-depressant medications (see Section 2.3 "Taking Remifemin® plus St. John's wort in combination with other medicinal products").

If you are already using Remifemin® plus St. John's wort, you should inform your physician in case he prescribes another medicine or if you wish to take an additional medicinal product yourself. In certain cases it may be necessary to consider discontinuing treatment with Remifemin® plus St. John's wort.

- Women using hormonal birth control (e.g. "the pill") and who are taking Remifemin® plus St. John's wort at the same time may experience metrorrhagia as a consequence of an interaction (s. Section 2.3). The reliability of hormonal birth control may be diminished and additional birth control measures should therefore be taken.
- You should avoid visiting tanning salons and exposure to excessive radiation from the sun while using Remifemin® plus St. John's wort.
- If surgery that requires partial or full anaesthesia is planned, consultation with a physician should take place at least one or two weeks in advance in order to identify possible interactions with the preparations being used. In this case, Remifemin® plus St. John's wort should be discontinued at least one week prior to surgery.

2.3 When taking Remifemin® plus St. John's wort together with other medicinal products:

Please inform your physician or pharmacist if you use / take or recently used / took other medicinal products, regardless of whether the products involved do not require a prescription.

Due to possible interactions, Remifemin® plus St. John's wort should not be taken with the medicinal products already listed in Section 2.1.

Remifemin® plus St. John's wort can interact with numerous other medicinal products, in that the concentration of such substances in the blood is lowered and their efficacy is thereby weakened. These substances include the following pharmaceutical ingredients:

- digoxin
- simvastatin
- fexofenadine
- benzodiazepine
- methadone
- *Hormonal birth control methods (contraceptives, e.g.* "the pill"), furthermore
- *other types of substances counteracting depression* such as
  - amitriptyline

Remifemin® plus St. John's wort can amplify serotonergic effects (such as e.g. nausea, vomiting, anxiety, restlessness, confusion) if it is combined with the following pharmaceutical agents:
other anti-depressants of the SSRI type, such as
- paroxetine
- sertraline

as well as – buspirone and
- triptans.

Simultaneous treatment with other medicinal products that exhibit photosensitizing effects may result in intensified phototoxic effects (see Section 4 "Side effects").

2.4 Pregnancy and breastfeeding:

Ask your physician or pharmacist for advice before taking medicinal products.
There are no relevant data to determine safety during pregnancy and breastfeeding. Due to insufficient data,

Please continue!

use during pregnancy or breastfeeding is not recommended.
Women of childbearing age should consider an effective, non-hormonal method of birth control during treatment (see Section 2.1).

2.5 Driving and operating machinery:
No studies have been carried out on the ability to drive and the operation of machinery.

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

3. How should Remifemin® plus St. John's wort be taken?

Always take Remifemin® plus St.John's wort exactly according to the instructions in the package leaflet. If you are in doubt, please ask your physician or pharmacist.

3.1 Insofar as the physician has not prescribed otherwise, the usual dosage is:
At the start of treatment (in the first eight weeks) two film-coated tablets twice daily, thereafter one film-coated tablet twice daily.

Based on the indication, use by children, adolescents and men is not intended.

There is insufficient data to determine definite dosage recommendations for cases of limited renal /liver function.

3.2 Method of administration:
The film-coated tablets are taken unchewed along with liquids in the morning and in the evening. You can take the film-coated tablets regardless of mealtimes.

3.3 Period of administration:
Remifemin® plus St. John's wort does not act immediately. An improvement in symptoms usually occurs after two to four weeks. It is recommended that Remifemin® plus St. John's wort be taken for several months, but no longer than six months unless advised by a physician. A physician should be consulted if psychological menopausal symptoms continue unchanged after six weeks.

Please talk to your physician or pharmacist if you feel that the effect of Remifemin® plus St. John's wort is too strong or too weak.

3.4 If you took a larger quantity of Remifemin® plus St. John's wort than you should have:
To date, no acute poisoning due to St. John's wort/a Cimifuga-preparation has been reported in humans. If a substantial overdose has been taken, the patient concerned should be protected from sunlight or UV radiation for a period of one to two weeks. The side effects as already described may intensify. You should consult your physician if you have significantly overdosed with this medicinal product.

3.5 If you forgot to take Remifemin® plus St. John's wort:
Do not take twice the dose, but instead continue taking it at the usual time.

Ask your physician or pharmacist if you have further questions on the use of the medicinal product.

4. What are the possible side effects?

As with all medicinal products, Remifemin® plus St. John's wort can result in side effects; these, however, may not occur in everyone.

The following frequency of occurrence data are used as a basis for evaluating side effects:

Very frequent:	can affect more than 1 of 10 users
Frequent:	can affect up to 1 of 10 users
Occasional:	can affect up to 1 of 100 users
Infrequent:	can affect up to 1 of 1,000 users
Very infrequent:	can affect up to 1 of 10,000 users
Unknown:	Frequency of occurrence cannot be evaluated based on available data

Possible side effects:

Infrequent:	– Gastrio-intestinal symptoms (upper abdominal symptoms, diarrhoea) – Allergic reactions of the skin (hives, itching, skin rash)
Very infrequent:	– (3-*sn*-phosphatidyl)choline (lecithin from soya beans) can cause allergic reactions very infrequently
Frequency of occurrence unknown:	– Cases of liver damage (including hepatitis, jaundice and disorders of liver function tests) from using Cimifuga-containing medicinal products – Increase in liver function tests (transaminases) – Facial swelling or swelling of limbs (facial- or peripheral oedema) – Weight gain – Sunburn-like skin reaction, especially in persons with fair complexions after intense UV radiation without adequate sun protection – Fatigue and unrest

In these cases you should discontinue the medicinal product and see your physician.

Reports of side effects:
Contact your physician or pharmacist if you notice side effects. This also applies to side effects that are not listed in the user information.
You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Pharmacovigilance Department,
Kurt-Georg-Kiesinger Allee 3
D-53175 Bonn
Website: http://www.bfarm.de
. By reporting side effects, you can contribute to having more information on the safety of this medicinal product made available.

5. How should Remifemin® plus St. John's wort be stored?

Store medicinal products out of reach of children.

The medicinal product may no longer be used after the expiration date that follows after "Use by" on the box. The expiration date refers to the last day of the indicated month.

Do not store over 25 °C.

6. Package contents and other information

What Remifemin® plus St John's wort contains:
The ingredients are:
One film-coated tablet contains
70 mg dry extract consisting of St. John's wort (3.5 – 6 : 1) extracting agent: ethanol 60 % (V/V) and 3.75 mg dry extract made of Cimifuga rootstock (6 – 11 : 1) extracting agent: Propan-2-ol 40 % (V/V).

Other components are:
microcrystalline cellulose, glycerol di behenate, highly disperse silicone dioxide, lactose monohydrate, lactose, poly(vinylalcohol), (3-*sn*-phosphatidyl)choline (soya beans), xanthane gum, talcum, colouring agents: Titanium dioxide (E 171), iron(III) oxide-hydroxide E 172, indigo carmine E 132.

Appearance of Remifemin® plus St. John's wort and contents of package:
Green, glossy, round film-coated tablets

Remifemin® plus St. John's wort can be purchased in packages of 60 (N2), 100 (N3), 120 and 180 film-coated tablets.

Pharmaceutical company and manufacturer
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