

Patient Information Leaflet: Information for the user

Remifemin® plus St. John's wort 70mg/3,75 mg film-coated tablets

for use in menopausal 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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this package leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse after 4 to 6 weeks.

What is written in this leaflet

1. What is Remifemin® plus St. John's wort and what is it used for
2. What you need to know before you take Remifemin® plus St. John's wort
3. How to take Remifemin® plus St. John's wort
4. Possible side effects
5. How to store Remifemin® plus St. John's wort
6. Contents of the pack and other information

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 for relief of menopausal complaints.

Remifemin® plus St. John's wort is used during menopause for relief of hot flushes and profuse sweating when these symptoms are accompanied by additional psychological menopausal complaints, e.g., depressive moods, nervousness, and irritability.

2. What you need to know before you take Remifemin® plus St. John's wort

2.1 Do not take Remifemin® plus St. John's wort

if you are hypersensitive (allergic) to Cimicifuga rhizome, St. John's wort, soy, peanuts, or any 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 being treated with another medicine that 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 Warnings and precautions

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

- if you already have a damaged liver (see section 4 Side effects). Then, you only should take Remifemin® plus St. John's wort after talking to your doctor.
- if signs and symptoms suggestive of liver damage (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 talk to a doctor.
- if you have been treated or you are undergoing treatment for breast cancer or other hormone-dependent tumors. In these cases, you should not take Remifemin® plus St. John's wort without medical advice.
- if you take medicines containing estrogen. Then, you should not take Remifemin® plus St. John's wort without medical advice.
- if you experience any menstrual disorders or bleeding occurs after being gone for at least 12 months or if the cause of the vaginal bleeding is unclear or unclear symptoms persist or other complaints reappear, 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 medicine: 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 certain cases, consideration should be given to stopping treatment with Remifemin® plus St. John's wort.

- Women who use hormonal contraceptive measures (e.g., "the pill") and simultaneously 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.
- At least 1 - 2 weeks before planned surgery with general or partial anesthesia 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.
- During the use of Remifemin® plus St. John's wort you should avoid excessive exposure to the sun and visiting the solarium.

2.3 Other medicines and Remifemin® plus St. John's wort

Please tell your doctor or pharmacist if you are taking, have recently taken or might use any other medicines.

Due to possible interactions do not take Remifemin® plus St. John's wort together with the medicines 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 possibly reducing their efficacy. The following agents belong to these substances:

- digoxin
- simvastatin
- fexofenadine
- benzodiazepines
- methadone
- *hormonal contraceptives (e.g., "the pill")*, and in addition
- *different medicine for depression* 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 SRI- or SSRI-type antidepressants such as:

- paroxetine
- Sertraline

as well as

- buspirone and
- triptanes

If given simultaneously with other medicines that increase photosensitivity (have a photosensitizing effect), an increase of 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 safety during pregnancy and breastfeeding. Therefore, use during pregnancy and breastfeeding is not recommended.

During treatment, women of child-bearing age should consider an effective non-hormonal contraception method (see section 2.1).

2.5 Driving and using machines

No studies have been performed on the ability to drive and use machines. Negative effects are not known.

2.6 Remifemin® plus St. John's wort contains lactose

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 do not tolerate certain sugars.

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

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

3.1 The recommended dose is

At the beginning of the treatment (during the first 8 weeks)
2x daily 2 film-coated tablets

Starting the 9th week
2x daily 1 film-coated tablet

Based on the indication, use in children, adolescents, and males is not intended.

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

3.2 Method of administration

Take the film-coated tablets with a liquid in the morning and in the evening. Do not chew. The film-coated tablets do not have to be taken with a meal.

3.3 Duration of use

Remifemin® plus St. John's wort does not work 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 for several months but no longer than 6 months without medical advice. If the psychological menopausal complaints remain unchanged after 6 weeks, medical advice should also be sought.

3.4 If you take more Remifemin® plus St. John's wort than you should

Acute intoxications with St. John's wort/Cimicifuga preparations in humans have not been reported so far. In case of a considerable overdose, you should protect yourself from sunlight and UV-radiation for the duration of 1 to 2 weeks. The listed side effects could be intensified. If you have taken a considerable overdose of this medicine, 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 taking at the usual time.

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

4. Possible side effects

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

Possible side effects

Rare: may affect up to 1 in 1,000 people	<ul style="list-style-type: none">- gastro-intestinal complaints (upper stomach pain, diarrhea)- allergic skin reactions (hives, itching, rash)
Not known: frequency cannot be estimated from the available data	<ul style="list-style-type: none">- cases of liver damage (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 edema)- weight gain- sunburn-like reactions of the skin, mainly in light-skinned persons after strong UV-radiation without sufficient sun protection- tiredness or restlessness

(3-*sn*-phosphatidyl)choline (lecithin from soy bean) may very rarely cause allergic reactions.

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

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This include any possible side effects not listed in this leaflet.

You may also report side effects directly to the
Bundesinstitut für Arzneimittel und Medizinprodukte
(*Federal Institute for Drugs and Medical Devices*)

Abt. Pharmakovigilanz
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn

Website: <http://www.bfarm.de>

By reporting side effects, you can help provide more information on the safety of this medicine.

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

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the pack after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C!

Do not throw away any medicines via wastewater (e.g., in the toilet or the sink). Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Further information can be found under www.bfarm.de/azneimittelentsorgung.

6. Contents of the pack and other information

What Remifemin® plus St. John's wort contains

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 (Ph. Eur.), colloidal anhydrous silica, lactose monohydrate, lactose, poly(vinylalcohol), (3-*sn*-phosphatidyl)choline (soybean), xanthan gum, talc, colorants: titanium dioxide (E 171), iron(III)-hydroxide oxide E 172, indigo carmine E 132

What 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 (N1), 100, 120 (N2) and 180 (N3) film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

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Dear Reader,

Menopausal symptoms such as hot flashes, excessive sweating, mood swings, nervousness, and irritability are natural but very unpleasant side effects of menopause in women over 40. Remifemin® plus St. John's wort is an herbal medicine from the pharmacy that can alleviate such symptoms.

How symptoms come about

The term menopause describes the natural phase in a woman's life in which the ability to have children slowly decreases. The activity of the ovaries gradually stops. The associated hormonal change is a natural process. In many women, however, the changes in the body are accompanied by significant complaints that should be treated.

The typical menopause symptoms include physical symptoms such as hot flashes and excessive sweating as well as psychological complaints such as moodiness, nervousness, and irritability. These can occur together or individually. In addition, irregularities in menstruation such as varying intervals or changes in the duration and severity of bleeding are the first signs of menopause.

The trigger for these symptoms is the declining ability of the ovaries to produce hormones (estrogen and progesterone). The fluctuating and falling estrogen levels affect the messenger balance in the brain. This in turn is considered to be the real cause of the menopausal symptoms.

Even if the natural decrease in hormone production plays an important role in the occurrence of menopausal symptoms, this does not mean that it is now necessary to take medicines containing hormones.

What is Remifemin® plus St. John's wort and how can it help you

With the herbal medicine Remifemin® plus St. John's wort, menopausal symptoms can be alleviated. Remifemin® plus St. John's wort contains a combination of extracts from the traditional medicinal plants black cohosh (*Cimicifuga racemosa*) and St. John's wort (*Hypericum perforatum*).

As you may already know from taking other herbal medicines, Remifemin® plus St. John's wort will not alleviate your symptoms immediately, but after about 2 to 4 weeks of regular use.

Remifemin® plus St. John's wort should be used continuously over a longer period of time. Important: Even, and especially, if you are doing well with the treatment, it is advisable not to take Remifemin® plus St. John's wort for longer than 6 months without medical advice. This is to prevent other diseases from being overlooked.

Tips on how you can support the treatment with Remifemin® plus St. John's wort

A healthy lifestyle can - like with other complaints - strengthen the body's self-regulating powers and contribute to an improved feeling of well-being for menopausal symptoms:

Eat and drink consciously: This includes a balanced, high-fiber, and vitamin-rich diet avoiding too many unhealthy fats. Using spicy spices, caffeine, and alcohol sparingly and not smoking are particularly helpful for hot flashes and sleep disorders. An adult should also drink about 2-3 liters of liquid a day. Calcium-rich water, fruit spritzers, or tea are recommended.

Exercise is good: Studies with women have shown that regular exercise has a positive impact on menopausal symptoms. A half-hour walk in the fresh air not only lets your body breathe, but also your soul. According to the motto "moderate but regular", experts consider 4 walks a week to be sufficient.

Reduce stress: Emotional distress and stress promote and intensify the occurrence of menopausal symptoms. Therefore, anything that reduces stress and soothes the soul can be helpful. Autogenic training, yoga or Jacobson's muscle relaxation technique are possible methods that can be used.

You can learn more about Remifemin® plus St. John's wort and menopausal complaints from Schaper & Brümmer, "Remifemin® - Service", Bahnhofstraße 35, 38259 Salzgitter.