

## Package leaflet: information for the user

### **Remifemin® mono** tablets for use in climacteric women dry extract of Cimicifuga rhizome

**Read all of this leaflet carefully before taking this medicine because it contains important information.**

Take this medicine always exactly as directed in this 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, consult your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.
- Contact your doctor if you do not feel better or if you feel worse after 21 days.

#### **In this leaflet:**

1. What Remifemin® mono is and what it is used for
2. Before you take Remifemin® mono
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#### **1. What Remifemin® mono is and what it is used for**

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

Remifemin® mono is used for relief of menopausal complaints such as hot flushes and profuse sweating.

#### **2. Before you take Remifemin® mono**

##### **2a) Do not take Remifemin® mono**

if you are hypersensitive (allergic) to Cimicifuga rhizome (Black Cohosh rootstock) or to any of the other ingredients of this medicine listed under section 6.

##### **2b) Warnings and precautions**

- If you have or had a liver disease (see section 4 "Side Effects"), you should take Remifemin® mono only after consultation with your doctor.
- If signs and symptoms suggestive of liver injury (yellowing of the skin or eyes, dark urine, upper stomach pain, nausea, loss of appetite, tiredness) occur, you should stop taking Remifemin® mono immediately and consult a doctor.
- If you experience any menstrual problems or your menstruation reappears, if unclear symptoms persist, if the symptoms worsen during the use of the medicine or if other symptoms newly occur, you should consult a doctor. This is because there may be evidence of illnesses that require investigation by a doctor.

- If you are treated with oestrogens, you should not take Remifemin<sup>®</sup> mono without medical advice.
- If you have been treated or you are undergoing treatment for breast cancer or other hormone-dependent tumours, you should not use Cimicifuga-preparations without medical advice.

**2c) Taking Remifemin<sup>®</sup> mono with other medicines**

Investigations regarding interactions with other medicines have not been performed. Up to now, no interactions have been known. Nevertheless, please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**2d) Pregnancy, breast-feeding and fertility**

There are no adequate data for assessing the safety during pregnancy and breast-feeding.

Therefore, the use during pregnancy and breast-feeding is not recommended.

Women of reproductive age should consider an effective contraceptive method during the treatment.

**2e) Driving and using machines**

No investigations have been made regarding the ability to drive and use machines.

**2f) Remifemin<sup>®</sup> mono contains lactose**

This medicine contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Remifemin<sup>®</sup> mono.

**3. How to take Remifemin<sup>®</sup> mono**

Always take Remifemin<sup>®</sup> mono exactly as directed in this package leaflet or as your doctor or pharmacist have told you. Please check with your doctor or pharmacist if you are not sure.

**3a) The recommended dose is**

for women in menopause **1 x daily 1 tablet.**

Please take the tablet unchewed with sufficient liquid (preferably a glass of drinking water).

You can take the tablet independently from the meals.

Due to the indication an application is not intended for children, adolescents and men.

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

**3b) Duration of use**

If the symptoms persist during the use of the medicine, you should consult a doctor or pharmacist.

Remifemin<sup>®</sup> mono does not reveal its effect immediately. The first therapeutic effects are apparent after two weeks of treatment at the earliest. It is advisable to take Remifemin<sup>®</sup> mono for several months, but not longer than 6 months without medical advice.

**3c) If you take more Remifemin<sup>®</sup> mono than you should**

In the event of overdose of Remifemin<sup>®</sup> mono, the listed side effects may increasingly occur. If this happens, you should stop taking the medicine and consult a doctor.

If none of these side effects occurs, continue taking the normal dose at the usual time.

**3d) If you forget to take Remifemin® mono**

Do not take a double dose, if you have forgotten the previous intake, but continue the intake at the usual time.

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

**4. Possible side effects**

Like all medicines, Remifemin® mono can cause side effects, although not everybody gets them.

There have been cases of liver injury during the use of medicines containing Cimicifuga. The frequency of these side effects is not known.

Allergic skin reactions (urticaria, pruritus, exanthema), swelling in the face or at the extremities (facial or peripheral oedema) and gastrointestinal complaints (upper abdominal pain, diarrhoea), increase in liver values as well as weight gain were reported.

The frequency is not known.

In these cases you should discontinue the medicine and consult your doctor.

**Reporting of side effects**

If you notice any side effects, please consult your doctor or pharmacist. This also applies to side effects not listed in this product information leaflet.

You can also report side effects directly to (*the national reporting system*). Reporting of side effects contributes to provide more information regarding the safety of this medicine.

**5. How to store Remifemin® mono**

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 30° C.

**6. Content of the pack and further information**

**What Remifemin® mono contains**

The active substance is:

*1 tablet contains*

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 (herbal)

**What Remifemin® mono looks like and contents of the pack**

Round, white to beige-coloured tablets

Remifemin® mono is available in packs containing 30, 60 and 90 tablets.

**Marketing authorisation holder and manufacturer**

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