

Package leaflet: Information for the user

Femicur® N

capsules

hard capsules

dry extract of chaste tree fruits

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 Femicur® N Capsules 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 90 days.
- 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 Femicur® N Capsules are and what are they used for
2. Before you take Femicur® N Capsules
3. How to take Femicur® N Capsules
4. Possible side effects
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1. What Femicur® N Capsules are and what they are used for

Femicur® N Capsules are a herbal medicine for the treatment of menstrual complaints.

Femicur® N Capsules are used for irregularities of the menstrual cycle (abnormal menses), monthly recurring complaints preceding the onset of the menstruation (premenstrual complaints), feeling of tension and swelling in the breasts (mastodynia).

2. Before you take Femicur® N Capsules

2.1 Do not take Femicur® N Capsules

- if you are hypersensitive (allergic) to chaste tree fruits or one of the other ingredients (see under 6. "Further information") of Femicur® N Capsules,
- if you have a tumour of the pituitary gland (hypophysial tumour),
- if you have breast cancer (mamma carcinoma),
- if you are pregnant or nursing.

2.2 Take special care with Femicur® N Capsules

- in case of menstrual disorders,
- in case of feeling of tension and swelling in the breasts.

In these cases you should first consult a doctor, because they may be evidence of illnesses that require investigation by a doctor.

2.3 Taking other medicines:

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine – even those not prescribed.

There is evidence that there could be a mutual weakening of the efficacy if medicines inhibiting a certain information system in the brain, so-called dopamine receptor antagonists, are applied at the same time.

2.4 Pregnancy and breast-feeding:

Femicur[®] N Capsules should not be taken during pregnancy and breast-feeding.

Animal experiments showed an impaired milk production after intake of chaste tree fruits.

2.5 Driving and using machines:

No special precautions necessary.

2.6 Important information about some of the other ingredients of Femicur[®] N Capsules:

This medicine contains lactose and glucose. 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 Femicur[®] N Capsules

Always take Femicur[®] N Capsules exactly as directed in this package leaflet. Please check with your doctor or pharmacist if you are not sure.

3.1 Unless otherwise prescribed by the doctor, the usual dose is: Once daily 1 hard capsule.

3.2 Mode of application:

Please take Femicur[®] N Capsules unchewed with sufficient liquid (preferably a glass of drinking water).

You can take the hard capsules irrespective of the meals.

3.3 Duration of use:

Take Femicur[®] N Capsules as curative application for several weeks (at least three menstrual cycles) until the complaints are alleviated or disappear.

Please ask your doctor or pharmacist if you have the impression that the effect of Femicur[®] N Capsules is too strong or too weak.

3.4 If you take more Femicur[®] N Capsules than you should, please contact a doctor.

Overdose effects have not been observed thus far.

3.5 If you forget to take Femicur[®] N Capsules:

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

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

4. Possible side effects

Like all medicines, Femicur[®] N Capsules 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 treated patient of 10
common:	1 to 10 treated patients of 100
uncommon:	1 to 10 treated patients of 1,000
rare:	1 to 10 treated patients of 10,000
very rare:	less than 1 treated patient of 10,000
unknown:	frequency not assessable on the basis of the available data

Possible side effects:

After intake of medicines containing chaste tree fruits headache, itching or abdominal disorders such as nausea, stomach pain or lower abdominal pain may occur as well as hypersensitivity reactions with skin rash and urtication. Severe reactions with face swelling, shortness of breath and swallowing difficulties have also been described.

There are no data on the frequency of these possible side effects.

Which counteractions have to be taken in case of side effects?

Especially if symptoms of hypersensitivity reactions occur, you should discontinue the use of Femicur[®] N Capsules and immediately consult your doctor.

After hypersensitivity reactions have occurred Femicur[®] N Capsules may not be taken again.

If you notice any side effects, contact your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via (...*the national reporting system*). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Femicur[®] N Capsules

Keep out of the reach and sight of children.

You should not use the medicine after the expiry date printed on the outer pack and on the blister after "use before". The expiry date refers to the last day of that month.

Storage conditions:

No special storage conditions are necessary for this medicine.

6. Further information

What Femicur[®] N Capsules contains:

Active substance:

1 hard capsule contains

4 mg dry extract of chaste tree fruits (7–13 : 1)

Extractant: ethanol 60 % (m/m)

The other ingredients are:

glucose syrup (dry substance), lactose monohydrate, talc, maize starch, magnesium stearate, colloidal anhydrous silica, gelatin, sodium laurilsulfate, purified water, colouring agents E 171 and E 172.

Note for diabetics: 1 hard capsule is equivalent to 0.007 bread units (BU).

What Femicur[®] N Capsules looks like and contents of the pack:

Light rose-coloured hard capsules.

Femicur[®] N Capsules are available in packs containing 30, 60 and 100 hard capsules.

Marketing authorisation holder and manufacturer

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This product information leaflet was last revised in November 2014.