

Femular®

Specific extract of Actaea racemosa Ze 450

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Femular. It does not contain all the available information. It does not take the place of talking to your health professional.

If you have any questions about taking this medicine, ask your health professional.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT FEMULAR IS USED FOR

Femular relieves menopausal symptoms.

About Femular

Femular contains a clinically proven extract of *Actaea racemosa* referred to as Ze 450. This exclusive formula has been extensively researched to relieve menopausal symptoms including hot flushes, night sweats, sleeplessness, tiredness, irritability, headache and mild anxiety. With its easy once daily dose, Femular provides relief during all stages of menopause.

Femular is well tolerated and scientific studies suggest it can relieve the symptoms of menopause without having an oestrogenic effect. Femular is manufactured in Switzerland using premium ingredients and has been used by millions of women worldwide.

Ask your health professional if you have any questions if you have any questions about why this medicine has been recommended for you.

Your health professional may have recommended it for another reason.

BEFORE YOU TAKE FEMULAR

When you must not take it

Do not take Femular if you have an allergy to:

- any medicine containing *Actaea racemosa* extract
- any of the ingredients listed at the end of this leaflet.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your health professional.

Before you start to take it

Tell your health professional if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your health professional if you have or have had any of the following medical conditions:

- liver disease or a history of liver damage
- breast cancer or other hormone-dependent tumours.

Tell your health professional if you have lactose intolerance.
Femular contains a small amount of lactose (44mg) per tablet.

Tell your health professional if you are going to have surgery.

Taking other medicines

Tell your health professional if you are taking any other medicines, including any that you get without a prescription.

There are no known interactions with other medicines and Femular.

Pregnancy and Breastfeeding

Do not take Femular if you are planning a pregnancy, are pregnant or breastfeeding.

Your health professional can discuss with you the risks and benefits involved or breastfeeding.

Children

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

HOW TO TAKE FEMULAR

Always take Femular as directed in this leaflet, or as recommended by a health professional. You should always check with your health professional if you are not sure.

If symptoms persist consult your health professional.

How much to take

Take 1-2 tablets daily depending on severity of menopausal symptoms.

The effect of Femular is usually seen within the first three months of treatment.

How to take it

Swallow the tablets with water.

When to take it

Adults take 1 or 2 tablets in the morning with or after a meal.

Take your medicine at about the same each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for 12 weeks or as long as your health professional tells you.

It is recommended that you check in with your health professional on a regular basis while you are taking Femular.

See your health professional if symptoms persist during use.

If you forget to take it

If it is less than 8 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your health professional.

If you have trouble remembering to take your medicine, ask your health professional for some hints.

If you take too much (overdose)

It is not necessary to take more Femular than the amount directed in the instructions of use, or by your health professional.

Telephone your health professional or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Femular, even if there are no signs of discomfort or overdose.

WHILE YOU ARE TAKING FEMULAR

Things you must do

If you are about to be started on any new medicine, remind your health professional that you are taking Femular.

Tell any other health professionals who treat you that you are taking this medicine, including your surgeon and anaesthetist if you are planning surgery.

If you become pregnant while taking this medicine, stop taking Femular and tell your health professional immediately.

Things you must not do

Do not take Femular to treat any other complaints unless your health professional tells you to.

Things that would be helpful

Some self help measures may help your condition. Your health professional can give you more information about these measures.

To find out more about how to effectively manage your menopausal symptoms visit flordis.com.au.

SIDE EFFECTS

Tell your health professional as soon as possible if you do not feel well while you are taking Femular.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Femular helps with the relief of menopausal symptoms but it may have unwanted side effects in a few people. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your health professional to answer any questions you may have.

Tell your health professional if you notice any of the following and they worry you:

- intermenstrual vaginal bleeding (such as 'spotting'), or
- recurrence of menstrual bleeding
- breast swelling or tension
- hives, rash, itching, or swelling of hands, ankles, feet or face
- gastrointestinal disturbance, such as indigestion, nausea or diarrhoea.

The above list includes the typical side effects of your medicine. They are usually mild and short-lived. If any of the above symptoms persist, see your health professional.

In very rare cases, Black cohosh has been associated with liver failure. The following list includes serious side effects that require medical attention. Tell your health professional immediately and stop taking Femular immediately if you notice any of the following: yellowing of the skin or whites of eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, severe upper stomach or abdominal pain, or loss of appetite. These serious side effects are very rare.

Other side effects not listed above may also occur in some people.

AFTER USING FEMULAR

FLORDIS™

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Keep Femular where children cannot reach it.

PRODUCT DESCRIPTION

What it looks like

Femular tablets are yellow beige biconvex tablets.

Ingredients

Each tablet of Femular contains:

- *Actaea racemosa* extract (Ze 450) 6.5.mg equivalent to dry root and rhizome 42.25 mg

Femular tablets contain a small amount of lactose (44 mg per tablet).

Femular contains no added gluten, wheat, yeast, soy, artificial flavours, colours or sweeteners.

Supplier

Femular is made in Switzerland by Max Zeller Söhne AG.

Femular is distributed in Australia by:

SFI Australasia

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St. Leonards, NSW, 2065 Australia
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