

Premular®

Specific extract of *Vitex Agnus-castus* Ze 440

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

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

All medicines have risks and benefits. Your health professional has weighed the risks of you taking Premular against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT PREMULAR IS USED FOR

Premular is used for the symptomatic relief of premenstrual syndrome (PMS).

About Premular

Premular is a natural medicine clinically proven to relieve PMS symptoms including irritability, anger, altered mood, headache, bloating and breast pain and tenderness.

Premular contains an exclusive extract of *Vitex agnus-castus* (Chaste tree) known as Ze 440 which has been the subject of multiple clinical trials. Evidence from these trials shows that Premular offers significant relief of PMS symptoms over a 3 month

period, and lasting relief for 3 cycles after therapy has ceased.

Premular works by modulating hormones and neurotransmitters involved in the menstrual cycle which are linked with symptoms of PMS.

With its easy one-a-day dose, Premular is convenient to take and has been used by millions of women worldwide.

This medicine is well tolerated and non-habit forming.

Ask your health professional 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 PREMULAR

When you must not take it

Do not take Premular if you have an allergy to:

- any medicine containing *Vitex agnus-castus* (Chaste tree)
- 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 suffer from any of the following conditions:

- Oestrogen sensitive cancer
- Pituitary-hypothalamic axis conditions
- Prolactin secreting tumours of the pituitary gland

Premular contains a very small amount of lactose (40mg per tablet). Those with lactose or galactose intolerance are advised to be cautious.

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

Taking other medicines

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

Although there are no known interactions with other medicines and Premular, caution is advised with:

- dopamine agonist and antagonist medication
- oestrogen and antioestrogen medication.

If you have not told your health professional about any of the above, tell him/her before you start taking Premular.

Pregnancy and breastfeeding

Tell your health professional if you are pregnant or plan to become pregnant or are breast feeding.

Premular is indicated for the symptoms of premenstrual syndrome and cycle disorders and is therefore not recommended in pregnancy and breast feeding.

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

HOW TO TAKE PREMULAR

Always take Premular 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

Adults and adolescents over 12 take 1 tablet each day at about the same time each day or as directed by your health professional.

How to take it

Swallow the tablet with water.

When to take it

Take Premular at about the same time each day, 1 hour before or after meals.

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

It does not matter if you take this medicine before or after food.

How long to take it

For best results take Premular for 3 months minimum.

If symptoms persist consult your health professional.

If you forget to take it

Skip the dose you missed and take your next dose when you are meant to.

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

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

If you take too much (overdose)

It is not necessary to take more Premular than the amount directed in this leaflet, 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 Premular, even if there are no signs of discomfort or overdose.

WHILE YOU ARE TAKING PREMULAR

Things you must do

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

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

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 relieve the symptoms of premenstrual syndrome visit flordis.com.au.

SIDE EFFECTS

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

Premular helps with the symptomatic relief of premenstrual syndrome but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of

the time they are not. You may need medical attention if you get some of the side effects.

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

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

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

- allergic reactions with face swelling, breathlessness and swallowing difficulties
- headache or dizziness
- gastrointestinal disturbance, such as nausea, abdominal pain
- skin rash, itchiness or acne
- menstrual disorders
- exacerbation of single symptoms of premenstrual syndrome in the initial treatment period.

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.

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

AFTER USING PREMULAR

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 the tablets protected from sunlight.

Keep Premular where children cannot reach it.

PRODUCT DESCRIPTION

What it looks like

Premular comes in a white round-shaped tablet.

Ingredients

Each tablet of Premular contains extract of *Vitex agnus-castus* Ze 440 equivalent to dry:

- *Vitex agnus-castus* extract 20 mg equiv. to dry fruit 180 mg

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

Premular tablets contain a small amount of lactose (40mg per tablet).

Supplier

Premular is made in Switzerland by Max Zeller Söhne AG.

Premular is distributed in Australia and South Africa by:

SFI Australasia

Level 2, 170 Pacific Highway,
St Leonards NSW 2065, Australia

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