Information Leaflet



Prostap® for Pre-Menstrual Dysphoric Disorder

What is Prostap®?

Prostap® is an injection. It contains a medicine called Leuprorelin, which is a Gonadotrophin-releasing hormone analogue (GnRHa). It works by reducing levels of estrogen and testosterone (sex hormones) in the body. These sex hormones are involved in the menstrual cycle.

It's given into the fat layer just under the skin. This can be in your arm, thigh, or tummy.

What is Prostap® used for?

Prostap® is 'licensed' to treat endometriosis. It's also licensed to treat some types of breast cancer. It's also used to treat prostate cancer in men.

The maker of Prostap® has shown its safe & effective when treating these conditions.

Is Prostap® licensed to diagnose or treat Pre-Menstrual Dysphoric Disorder (PMDD)? Prostap® is not licensed to treat PMDD. This means the leaflet that comes in the box won't talk about PMDD. This is also called 'off-label' use of a medicine.

Off-label means that the medicine is used differently than stated in its licence. If your doctor thinks you need an off-label medicine, this means that they think it's safe and effective for you. This is often based on guidelines, and their experience. This is very important as there are very few ways to successfully treat PMDD.

Why am I being offered Prostap® to diagnose or treat PMDD?

You might be offered Prostap® for 3 months to help your doctor decide if you have PMDD.

Prostap® will temporarily stop your ovaries from producing hormones, causing a reversible 'medical menopause'. Your PMDD symptoms may go away during this time. If this happens, it's likely you have PMDD and you will be offered further treatment.

You may be given Prostap® to help PMDD symptoms if other treatments haven't worked. Other PMDD treatments include antidepressants and combined birth control pills.

How often is Prostap® given?

Prostap® comes as:

- a once-monthly injection (containing 3.75mg of Leuprorelin) and
- a three-monthly injections (containing 11.25mg of Leuprorelin).

You are usually given the once-monthly injection first. This is to make sure it helps your symptoms and doesn't cause side effects. You can have the three-monthly injection after this if you want. This means you attend hospital less often.

How long will I use Prostap® for?

Your PMDD symptoms will come back when your last Prostap® injection wears off. It normally wears off one to three months after the last injection. If Prostap® is the only thing that helps you, you can use it long-term.

Are there risks in using Prostap® long-term?

Yes, there are risks of using Prostap® long-term. Prostap® will give you symptoms of menopause. This includes hot flushes and weaker bones. These symptoms are more likely if you take Prostap® for at least six months.

Your doctor will give you hormone replacement therapy (HRT) to stop these symptoms. This is usually tablets containing a medicine called Tibolone. It is very important that you take HRT if your doctor gives you it.

Will I need to have bone scans if I use Prostap® long-term?

Yes. The HRT you take alongside Prostap® will help protect your bones from becoming weak. If you use Prostap® for over two years, you will need a bone scan. You will then need to have a bone scan every year after this.

If a scan shows your bones are becoming weak, you may have to stop it.

How else can I protect my bones whilst taking Prostap®?

Make sure take your HRT as prescribed. Get bone scans when asked to by your doctor.

- Take regular exercise. This is at least 2.5 hours of moderate-intensity aerobic exercise each week. This could be fast walking or cycling. Weight-bearing exercise is also important, such as running, jogging, tennis, badminton or keep-fit classes.
- Eat a healthy, balanced diet. Get at least 700mg of calcium each day. calcium-rich foods include green leafy vegetables, dairy, dried fruit and tofu. You should get at least 10mcg of vitamin D each day. Foods with vitamin D include oily fish, red meat and fortified foods (foods with added vitamin D). You can also take a vitamin D supplement.
- Stop smoking.
- Limit how much alcohol you drink. The NHS says don't drink more than 14 units a week. You should avoid binge drinking.

What are the other possible side effects of Prostap®

Most side effects of Prostap® are due to reduced estrogen levels in your blood.

Common side effects of Prostap® include hot flushes, mood swings, depression, and vaginal dryness. You can also get headaches, tiredness, weight changes, mood changes, breast tenderness. You can get skin reactions where the injection is given. These include skin hardening, redness, pain, abscesses, swelling, nodules, ulcers, and skin damage). Your periods are also likely to stop.

Please speak to your doctor if you are worried about side effects. All side effects are listed in the box patient information leaflet. Your nurse or doctor will offer you the leaflet after each injection.

Is Prostap® a form of birth control?

Although Prostap® causes most women's periods to stop, it doesn't work as birth control. The HRT given alongside it is not birth control either. Please use non-hormonal methods of contraception, such as condoms, whilst on Prostap®.

Will Prostap® affect my fertility?

No. Prostap® is reversible. Your fertility will go back to normal after your last injection wears off.

Where can I get further information?

If you have any further questions, please speak to your doctor, nurse or pharmacist. You can also find information on PMDD on the RCOG website at: <u>www.rcog.org.uk/for-the-public/browse-our-patient-information/managing-premenstrual-syndrome-pms</u>.

This leaflet can be changed into different languages and formats using the tools on the website. Please note when translating information into different languages via the website, some information may need clarifying for accuracy with a member of staff. This leaflet can be formally translated on request via our Patient Experience Team, although response times to have information translated can vary. To request formal translation services or if you would like to make any suggestions or comments about the content of this leaflet, please contact the Patient Experience Team on 0151 702 4353 or by email at pals@lwh.nhs.uk

Liverpool Women's NHS Foundation Trust Crown Street Liverpool L8 7SS

Tel: 0151 708 9988 Issue Date: 14/03/2025 Reference: Gyn_2025-394-v1 Review Date: 14/03/2028 © Liverpool Women's NHS Foundation Trust