



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Intrarosa

## prasterone

This is a summary of the European public assessment report (EPAR) for Intrarosa. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Intrarosa.

For practical information about using Intrarosa, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Intrarosa and what is it used for?

Intrarosa is a medicine used to treat postmenopausal women with moderate to severe symptoms of vulvar and vaginal atrophy. In women with vulvar and vaginal atrophy, the wall of the vagina and surrounding tissues become thinner and can cause symptoms such as dryness, irritation and soreness around the genital area, and painful sexual intercourse.

Intrarosa contains the active substance prasterone, also known as dehydroepiandrosterone (DHEA).

### How is Intrarosa used?

Intrarosa is available as a 6.5 mg pessary. Women should insert the pessary into their vagina, once daily, at bedtime.

The medicine can only be obtained with a prescription. For further information, see the package leaflet.

### How does Intrarosa work?

In women who have been through the menopause, the thinning of the tissues in and around the vagina is caused by a fall in levels of the sex hormone oestrogen.



The active substance of Intrarosa, prasterone, is converted into the sex hormones oestrogens and androgens when inserted into the vagina. As a result of increasing oestrogen levels, the number of superficial cells in the tissues in and around the vagina increases thus relieving the symptoms of vaginal atrophy.

### **What benefits of Intrarosa have been shown in studies?**

Two studies involving 813 post-menopausal women with vulvar and vaginal atrophy found that treatment with Intrarosa was more effective than placebo (a dummy treatment) at reducing signs of thinning (atrophy) of vaginal tissues.

In both studies, 6.5 mg Intrarosa was given once a day for 12 weeks. Results showed that the number of superficial cells (which normally falls with atrophy) increased by 6% and 10% with Intrarosa compared with about 1% and 2% with placebo. There was also a decrease in the number of parabasal cells (which normally increase with atrophy) of 42% and 47% with Intrarosa compared with 2% and 12% with placebo.

In addition, Intrarosa treatment was better at increasing acidity in the vagina (which normally becomes less acidic with atrophy), with pH values reducing by 0.9 and 1.0 with Intrarosa and by 0.2 and 0.3 with placebo.

Patients taking Intrarosa had a modest reduction in pain during sexual intercourse, which was similar or better to the effect seen in patients taking placebo. Pain during sexual intercourse was self-assessed by patients using a standard scale ranging from 0 (no pain) to 3 (severe pain). The pain reduced by 1.3 and 1.4 points with Intrarosa compared with 0.9 and 1.1 points with placebo. The effect seen in the placebo group was explained by the lubricant effect of the excipient.

### **What are the risks associated with Intrarosa?**

The most common side effect with Intrarosa (which may affect up to 1 in 10 people) is vaginal discharge. For the full list of side effects reported with Intrarosa, see the package leaflet.

Intrarosa must not be used in patients with the following conditions: genital bleeding where the cause has not been diagnosed, known or suspected breast cancer or oestrogen-dependent cancer, previous breast cancer, untreated endometrial hyperplasia (thickening of the lining of the womb), acute (short-term) liver disease, previous liver disease where liver function tests are still abnormal, previous or current venous thromboembolism (formation of blood clots in the veins), thrombophilic disorders (abnormal blood clotting), active or recent arterial thromboembolic disease (disease caused by blood clots in the arteries), porphyria (inability to break down chemicals called porphyrins). For the full list of restrictions, see the package leaflet.

### **Why is Intrarosa approved?**

Intrarosa has been shown to improve the structure of the vaginal tissues and to have a modest effect on pain during sexual intercourse. The medicine has an acceptable safety profile.

The European Medicines Agency therefore considered that Intrarosa's benefits are greater than its risks and recommended that it be approved for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Intrarosa?**

The company that markets Intrarosa is required to conduct a study on how the medicine is used in clinical practice, including whether it is used according to the authorised product information.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Intrarosa have also been included in the summary of product characteristics and the package leaflet.

## **Other information about Intrarosa**

The European Commission granted a marketing authorisation valid throughout the European Union for Intrarosa on 8 January 2018.

The full EPAR for Intrarosa can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Intrarosa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2018.