

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)**INTRINSA****EPAR summary for the public**

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Intrinsa?

Intrinsa is a transdermal patch (a patch that delivers a medicine across the skin). The patch releases 300 micrograms of the active substance testosterone over 24 hours.

What is Intrinsa used for?

Intrinsa is used to treat women who have had their uterus (womb) and both ovaries removed, when they have a lack of sexual thoughts and sexual desire that is causing them distress. It is used in patients already taking an oestrogen (a female sex hormone).

The medicine can only be obtained with a prescription.

How is Intrinsa used?

Intrinsa is used as a continuous treatment, as one patch twice a week. The patch is applied to dry, clean skin on the lower abdomen (the tummy, below the waist). The patch remains on the skin for three or four days and is then replaced by a new patch in a different place. The same place must not be used again until at least seven days later. It may take longer than a month for the patient to see an improvement. If a patient is not getting a benefit after three to six months of treatment, she should contact her doctor and have her treatment reviewed.

How does Intrinsa work?

The active substance in Intrinsa, testosterone, is a natural sex hormone produced in men and, to a lesser extent, in women. Low testosterone levels have been linked to low sexual desire and to reduced sexual thoughts and arousal. In women who have had their uterus and ovaries removed, the amount of testosterone produced is halved. Intrinsa releases testosterone through the skin into the bloodstream to produce testosterone levels that match the levels seen before removal of the uterus and ovaries.

How has Intrinsa been studied?

Because testosterone is a well-known substance that is already used in other medicines, the company used data from the published literature as well as carrying out studies itself. The two main studies involved 1,095 women with an average age of 49 years who received Intrinsa for up to a year. Intrinsa was compared with placebo (a patch containing no active substance). The studies used a specially designed questionnaire to measure sexual interest and activity by recording the number of satisfying

sexual episodes in a four-week period. The main measure of effectiveness was based on the change in the questionnaire score before the study began and after six months of treatment.

What benefit has Intrinsa shown during the studies?

Intrinsa was more effective than placebo. When the results of the two studies were looked at together, the women who used Intrinsa had an average of 1.07 more satisfying sexual episodes than the women who used placebo over a four-week period. On average, women who had three satisfying sexual episodes in a four-week period before treatment had around five episodes over four weeks after using Intrinsa for six months. In contrast, women who used placebo had around four episodes in a four-week period after six months.

What is the risk associated with Intrinsa?

The most common side effects with Intrinsa (seen in more than 1 patient in 10) are hirsutism (increased hair growth, especially on the chin and upper lip), and reactions at the site of application of the patch (redness and itching). For the full list of all side effects reported with Intrinsa, see the Package Leaflet. Because testosterone is a male sex hormone, women who are taking Intrinsa should be monitored to see if they develop any 'androgenic' side effects (development of male characteristics) such as hair growth on the face, deepening of the voice or hair loss. Women should contact their doctor if they notice any of these effects.

Intrinsa should not be used in people who may be hypersensitive (allergic) to testosterone or any of the other ingredients. It should also not be used in women who have, or have had breast cancer or another oestrogen-dependent cancer, or who have other conditions that mean that they cannot take oestrogen-containing medicines.

Women using Intrinsa should also use oestrogens, but not of the type known as 'conjugated oestrogens' as this combination is not as effective.

Why has Intrinsa been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Intrinsa's benefits are greater than its risks for the treatment of hypoactive sexual desire disorder in bilaterally oophorectomised and hysterectomised women receiving concomitant oestrogen therapy. The Committee recommended that Intrinsa be given marketing authorisation.

Which measures are being taken to ensure the safe use of Intrinsa?

The company that makes Intrinsa will monitor some of the side effects of Intrinsa closely, such as androgenic side effects. The company will review all ongoing studies with Intrinsa to look at potential long-term risks including breast cancer, endometrial cancer (cancer of the lining of the womb) and side effects affecting the heart and blood vessels. The company will also provide an educational plan for doctors and patients.

Other information about Intrinsa:

The European Commission granted a marketing authorisation valid throughout the European Union for Intrinsa to Procter & Gamble Pharmaceuticals UK Ltd. on 28 July 2006.

The full EPAR for Intrinsa can be found [here](#).

This summary was last updated in 05-2008.