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EPAR summary for the public

Intrinsa

testosterone

This document is a summary of the European public assessment report (EPAR) for Intrinsa. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Intrinsa.

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 lack of sexual thoughts and desire that is causing distress in women who have had their womb and both ovaries removed. 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 feel an improvement. If a patient does not feel any improvement after three to six months of treatment, she should contact her doctor and have her treatment reviewed.

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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 womb 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 womb 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 must 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' because the combination of these with Intrinsa is not as effective as the combination of other types of oestrogen with Intrinsa.

Why has Intrinsa been approved?

The CHMP decided that Intrinsa's benefits are greater than its risks and recommended that it be given marketing authorisation.

What information is still awaited for Intrinsa?

The company that makes Intrinsa will monitor some of the side effects of Intrinsa closely, such as its androgenic side effects. The company will review all of the 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 on 28 July 2006. The marketing authorisation holder is Warner Chilcott UK Ltd. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Intrinsa can be found here. For more information about treatment with Intrinsa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2010.