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Senshio *(ospemifene)*

An overview of Senshio and why it is authorised in the EU

What is Senshio and what is it used for?

Senshio is a medicine used to treat moderate to severe symptoms of vulvovaginal atrophy (dryness, irritation and soreness around the genital area, and painful sexual intercourse) in women who have been through menopause.

Senshio contains the active substance ospemifene.

How is Senshio used?

Senshio is available as tablets (60 mg). The recommended dose is one tablet once a day taken with food and at the same time each day.

The medicine can only be obtained with a prescription.

For more information about using Senshio, see the package leaflet or contact your doctor or pharmacist.

How does Senshio work?

Oestrogen hormones help to maintain the health of tissue in and around the vagina. As the levels of oestrogen hormones fall during menopause, the vaginal lining may become thin and dry. This can cause irritation and soreness and make sexual intercourse painful. The active substance in Senshio, ospemifene, is a selective oestrogen receptor modulator (SERM). This means that it acts in the same way as oestrogen in some tissues in the body such as the vagina and so helps to reduce symptoms of vulvovaginal atrophy. However, ospemifene does not work in the same way in other tissues such as the breast and womb, where such activity could cause hyperplasia (growth) of tissues which could lead to cancer.

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What benefits of Senshio have been shown in studies?

Senshio has been compared with placebo (a dummy treatment) in two main studies involving over 1,700 postmenopausal women with vulvovaginal atrophy. The main measure of effectiveness was related to the change in symptoms such as pain associated with sexual activity and vaginal dryness, using a validated questionnaire. Women also received non-hormonal vaginal lubricant for use as needed. In the first study, 66% of women using Senshio reported relief from vaginal dryness (mild or no symptoms) after 12 weeks treatment compared with 49% in the placebo group. In the second study, 62% of women using Senshio reported relief from vaginal dryness after 12 weeks (compared with 53% in the placebo group). Regarding pain during sexual activity, 58% of women using Senshio reported relief in the first study (compared with 42% receiving placebo) and 63% reported relief during the second study (compared with 48% receiving placebo). The studies also showed that Senshio was effective in restoring the vaginal environment including its acidity and thickness of the lining.

What are the risks associated with Senshio?

The most commonly reported side effects with Senshio (affecting up to 1 in 10 people) are vulvovaginal candidiasis and other mycotic (fungal) infections, hot flushes, headache, muscle spasms, mild vaginal bleeding, vaginal and genital discharge, and rash.

Some women must not use Senshio, including those who have or have had problems with blood clots in veins such as deep-vein thrombosis (DVT), pulmonary embolism (a blood clot in the lungs) and retinal-vein thrombosis (a blood clot at the back of the eye). Senshio must also not be used in women who have breast cancer or another cancer that is sex hormone-dependent such as endometrial cancer (cancer of the womb). In addition, it must not be used in patients with unexplained vaginal bleeding or patients with endometrial hyperplasia (abnormal thickening of the lining of the womb).

For the full list of side effects and restrictions of Senshio, see the package leaflet.

Why is Senshio approved?

The European Medicines Agency decided that Senshio's benefits are greater than its risks and it can be authorised for use in the EU. Senshio improved symptoms of vulvovaginal atrophy in postmenopausal women. The Agency noted that the degree of improvement with Senshio was comparable to that with oestrogen treatments that are applied to the vagina. Since Senshio is given by mouth the Agency considered that this medicine is a valuable alternative to local treatment. In addition, the Agency considered that the safety profile of Senshio was in line with medicines working in a similar way (SERMs).

What measures are being taken to ensure the safe and effective use of Senshio?

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

As for all medicines, data on the use of Senshio are continuously monitored. Side effects reported with Senshio are carefully evaluated and any necessary action taken to protect patients.

Other information about Senshio

Senshio received a marketing authorisation valid throughout the EU on 15 January 2015.

Further information on Senshio can be found on the Agency's website: www.ema.europa.eu/medicines/human/EPAR/senshio.

This overview was last updated in 03-2022.