

Package leaflet: Information for the patient

Senshio 60 mg film-coated tablets ospemifene

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Senshio is and what it is used for
2. What you need to know before you take Senshio
3. How to take Senshio
4. Possible side effects
5. How to store Senshio
6. Contents of the pack and other information

1. What Senshio is and what it is used for

Senshio contains the active substance ospemifene. Ospemifene belongs to a group of medicines that do not contain hormones called Selective Estrogen Receptor Modulators (SERMs).

Senshio is used to treat women with moderate to severe post-menopausal symptoms in and outside the vagina, such as itching, dryness, burning and pain during sex (dyspareunia). This is known as vulvar and vaginal atrophy. It is caused by a lowering in the levels of the female hormone oestrogen in your body. When this happens, the vaginal walls can become thinner. This happens naturally after menopause (post-menopause).

Senshio works in a similar way to some of the helpful effects of oestrogen, helping to improve these symptoms and the underlying causes of vulvar and vaginal atrophy.

2. What you need to know before you take Senshio

Do not take Senshio

- If you are allergic to ospemifene or any of the other ingredients of this medicine (listed in section 6).
- If you have or have ever had a **blood clot in a vein** (thrombosis), for example, in your legs (deep vein thrombosis), lungs (pulmonary embolism), or eyes (retinal thrombosis).
- If you have **unexplained vaginal bleeding**.
- If your doctor thinks you might have **breast cancer** or you are being treated for breast cancer.
- If your doctor thinks you might have or you are being treated for **cancer which is sensitive to oestrogens**, such as cancer of the womb.
- If you have **excessive thickening of the womb lining**, such as endometrial hyperplasia.

Warnings and precautions

Once you have started on Senshio you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Senshio.

Talk to your doctor or pharmacist before taking Senshio if any of the following apply to you.

- Any of your close relatives has ever had a blood clot in the leg, lung or other organ.
- You are seriously overweight (BMI >30 kg/m²).
- You have an autoimmune condition called systemic lupus erythematosus (SLE).
- If you have had a stroke (a cerebrovascular accident), or if your doctor has told you that you are at high risk of having one.
- If you are suffering from any gynaecological illness other than vulvar and vaginal atrophy.
- If you have had breast cancer.

While taking Senshio:

- If you are unable to walk for a long time or are sitting for a long time in the same position because of major surgery, injury or illness, it may prevent good blood circulation and may temporarily increase your risk of blood clots. You should therefore speak to your doctor immediately. Your doctor may recommend that you stop treatment at least 4 to 6 weeks prior to major surgery or during a long period of bed rest e.g. injury or illness. Treatment with Senshio can be restarted as soon as you regain your mobility and in consultation with your doctor.
- If any vaginal bleeding occurs while taking Senshio or soon after you have stopped taking it, **you should speak to your doctor.**
- If you experience signs of a blood clot, such as painful swelling and redness of the legs, sudden chest pain, difficulty in breathing or a stroke while taking Senshio, **stop taking Senshio and see a doctor immediately.**

Children and adolescents

Do not give this medicine to children or adolescents. This medicine is only intended for use in postmenopausal women.

Other medicines and Senshio

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Senshio with any of these medicines:

- Oestrogens.
- Any other medicine belonging to the group called SERMs, such as tamoxifen, toremifene, bazedoxifene and raloxifene.

Talk to your doctor before taking Senshio with:

- Fluconazole (an oral medicine used to treat fungal infections) as this may increase the amount of ospemifene in your blood. Your doctor may consider stopping treatment with Senshio while you are taking fluconazole.
- Any of the following medicines, which may lead to a reduced effect of Senshio:
 - Rifampicin and rifabutin commonly used to treat tuberculosis.
 - Carbamazepine and phenytoin used to treat convulsions/seizures (anticonvulsants).
 - St John's wort, a herbal medicine sometimes used to treat depression.
 - Orlistat sometimes used to treat obesity.
- Any of the following medicines, as their concentrations may be increased while taking Senshio:
 - Metformin used to treat Type II diabetes.
 - Aciclovir used to treat cold sores and genital herpes.
 - Ganciclovir used to treat infections caused by a virus called cytomegalovirus.
 - Oxaliplatin, an anti-cancer medicine for advanced (metastatic) cancer of the large bowel (colon) or back passage (rectum).

Pregnancy, breast-feeding and fertility

Senshio is for use only in postmenopausal women. It must not be taken by women who are pregnant, who could still have a baby or are breast-feeding. This is because there are no data on the use of Senshio in pregnant or pre-menopausal women or those who are breast-feeding.

Tell your doctor immediately if you become pregnant while taking Senshio; treatment should be stopped immediately.

Driving and using machines

Senshio has no known or very little influence on the ability to drive and use machines.

Senshio contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Senshio contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Senshio

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet taken orally at the same time each day. Senshio should be taken with food. The tablets should be swallowed whole with food.

Senshio must be taken every day for as long as your doctor tells you to.

Patients with liver disease

This medicine is not recommended if you have severely reduced liver function.

If you take more Senshio than you should

If you take more tablets than you should, tell your doctor or pharmacist.

If you forget to take Senshio

If you forget to take a tablet you should take the missed tablet (with food) as soon as you remember within the same day. Do not take two tablets in one day to make up for a forgotten tablet.

If you stop using Senshio

You will not benefit from the effects of Senshio if you stop using it without talking to your doctor. Your doctor will explain the effects of stopping treatment and will also discuss other possibilities for treatment with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect up to 1 in 10 people):

- An infection of the genitals caused by a fungus (thrush)
- Hot flushes
- Muscle cramps
- Vaginal or genital discharge
- Rash
- Headache
- Vaginal bleeding

Uncommon side effects (may affect up to 1 in 100 people):

- Thickening of the womb lining (endometrium) as seen on ultrasound scan (endometrial hypertrophy).
- An allergic reaction. Symptoms of an allergic reaction may include rash, itchy skin, raised patches on your skin (urticaria), swelling of the tongue and throat that may cause difficulty in breathing or swallowing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Senshio

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Senshio contains

- The active substance is ospemifene. Each film-coated tablet contains 60 mg ospemifene.
- The other ingredients are:
 - Tablet core:** Colloidal silicon dioxide (E 551), magnesium stearate (E 578), mannitol (E 421), microcrystalline cellulose (E 460), povidone (E 1201), pregelatinised starch (maize), sodium starch glycolate (type A).
 - Film coating:** Hypromellose (E 464), lactose monohydrate, titanium dioxide (E 171), triacetin (E 1518), polyethylene glycol (E 1521).

What Senshio looks like and contents of the pack

Senshio tablets are oval biconvex, white to off-white, film-coated tablets (approximately 12 mm long by 6.45 mm wide) debossed with “60” on one side.

They are packed in blisters and are available in pack sizes of 7, 28 or 84 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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