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Senstend (*lidocaine / prilocaine*)

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

What is Senstend and what is it used for?

Senstend is a medicine containing the active substances lidocaine and prilocaine. It is used to treat men with primary (lifelong) premature ejaculation (when ejaculation regularly occurs before, or too early during, penetration).

This medicine is the same as Fortacin, which is already authorised in the EU. The company that makes Fortacin has agreed that its scientific data can be used for Senstend ('informed consent').

How is Senstend used?

Senstend can only be obtained with a prescription and is available as a spray-on solution that supplies 7.5 mg of lidocaine and 2.5 mg of prilocaine per spray. The recommended dose is three sprays onto the head (glans) of the penis before intercourse. Doses should not be repeated more frequently than every 4 hours, and no more than three doses should be used in 24 hours.

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

How does Senstend work?

The active substances in the medicine, lidocaine and prilocaine, are local anaesthetics that temporarily numb the contact area by reversibly blocking the transmission of signals in the nerves. This reduces sensitivity to stimulation, and when applied onto the head of the penis this will help to increase the time taken to ejaculate.

What benefits of Senstend have been shown in studies?

The effectiveness of Senstend has been shown in two main studies involving 256 and 300 heterosexual adult men with premature ejaculation, respectively; both studies compared the medicine with a placebo (dummy) spray over 12 weeks. The main measures of effectiveness were the time taken to ejaculate after penetration and the amount of control over ejaculation, sexual satisfaction and distress reported by the patients. In the first study, the average time to ejaculation in patients treated with Senstend was 2.6 minutes, compared with 0.8 minutes in those using placebo; in the second study,

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average ejaculation time in patients using the medicine was 3.8 minutes compared with 1.1 minute in the placebo group. In both studies, patients given the medicine reported substantially greater improvements in reported control, sexual satisfaction and distress than patients given the placebo. Some patients were monitored for up to 9 months in an extension of the initial studies and continued to show similar benefit.

What are the risks associated with Senstend?

The most common side effects with Senstend (which may affect up to 1 in 10 people) are hypoaesthesia (reduced sensation) and a burning sensation in the genital area in both men and their female sexual partners, and erectile dysfunction (inability to maintain a normal erection) in men. For the full list of side effects reported with Senstend, see the package leaflet.

Senstend must not be used in patients who are hypersensitive (allergic) to any of the ingredients of the medicine or to other local anaesthetics with a structure related to the active ingredients (amide-type local anaesthetics). Senstend must also not be used in patients whose partners are hypersensitive to these substances.

Why is Senstend authorised in the EU?

The European Medicines Agency considered that the active ingredients are a well-known local anaesthetic combination, and the use of a local spray minimises the amount of active substance absorbed and hence the risk of side effects affecting the body as a whole. There were also positive psychological benefits to patients and their partners, and side effects were local and generally manageable. The Agency therefore decided that Senstend's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Senstend

Senstend received a marketing authorisation valid throughout the EU on 14 November 2019.

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

This overview was last updated in 09-2019.