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Fortacin[1] (*lidocaine/prilocaine*)

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

What is Fortacin and what is it used for?

Fortacin is used to treat men with primary (lifelong) premature ejaculation (when ejaculation regularly occurs before, or too early during, penetration).

Fortacin contains the active substances lidocaine and prilocaine.

How is Fortacin used?

Fortacin can be obtained without 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 3 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 3 doses should be used in 24 hours. For more information about using Fortacin, see the package leaflet or contact your doctor or pharmacist.

How does Fortacin work?

The active substances in the medicine, lidocaine and prilocaine, are local anaesthetics that temporarily numb the contact area by blocking the transmission of signals in the nerves. This reduces sensitivity to stimulation, helping to increase the time taken to ejaculate.

What benefits of Fortacin have been shown in studies?

The effectiveness of Fortacin 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 control over ejaculation, sexual satisfaction and distress reported by the patients. In the first study, the average time to ejaculation in patients treated with Fortacin was 2.6 minutes, compared with 0.8 minutes in those using placebo; in the second study, average ejaculation time in patients using the medicine was 3.8 minutes compared with 1.1 minutes 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.

[1] Previously known as Lidocaine/Prilocaine Plethora.

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Some patients from the main studies were monitored for up to 9 and Fortacin continued to show similar benefit.

What are the risks associated with Fortacin?

The most common side effects with Fortacin (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 sexual partners, and erectile dysfunction (inability to maintain a normal erection) in men. For the full list of side effects with Fortacin, see the package leaflet.

Fortacin must not be used in patients who are hypersensitive (allergic) to other local anaesthetics which are chemically similar with the active ingredients (amide-type local anaesthetics). Fortacin must also not be used in patients whose partners are hypersensitive to these substances. For the full list of restrictions, see the package leaflet.

Why is Fortacin approved?

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 positive psychological benefits to patients and their partners, and side effects were generally manageable and confined to the area coming into contact with the medicine. The Agency therefore decided that Fortacin'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 Fortacin?

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

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

Other information about Fortacin

Lidocaine/Prilocaine Plethora received a marketing authorisation valid throughout the EU on 15 November 2013.

The name of the medicine was changed to Fortacin on 26 September 2014.

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

This overview was last updated in 08-2020.