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EPAR summary for the public

Fortacin

lidocaine / prilocaine

This is a summary of the European public assessment report (EPAR) for Fortacin. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Fortacin.

For practical information about using Fortacin, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fortacin and what is it used for?

Fortacin 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).

How is Fortacin used?

Fortacin 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 further information, see the package leaflet.

How does Fortacin 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, helping to increase the time taken to ejaculate.

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What benefits of Fortacin have been shown in studies?

The effectiveness of Fortacin has been shown in two main studies involving a total of 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 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. 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 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 female sexual partners, and erectile dysfunction (inability to maintain a normal erection) in men. For the full list of all side effects reported with Fortacin, see the package leaflet. Fortacin 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). Fortacin must also not be used in patients whose partners are hypersensitive to these substances.

Why is Fortacin approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) 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 local and generally manageable. The CHMP therefore decided that Fortacin's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Fortacin is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Fortacin, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Fortacin

The European Commission granted a marketing authorisation valid throughout the European Union for Fortacin on 15 November 2013.

The full EPAR for Fortacin can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Fortacin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09/2014.