Summary Public Assessment Report

non-generics

Alprostadil Recordati 2 mg/g and 3 mg/g, cream

(Alprostadil)

NL/H/3303/001-002/DC

Date: 21 December 2017

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Active substance: alprostadil

This is a summary of the public assessment report (PAR) for Alprostadil Recordati. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Alprostadil Recordati.

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

What is Alprostadil Recordati and what is it used for?
Alprostadil Recordati is a cream that can be used to treat erectile dysfunction (ED). ED is the inability to attain or maintain an erection sufficient for sexual intercourse.

How does this medicine work?
For attaining and maintaining an erection, the blood vessels entering the penis need to widen, allowing more blood to enter. This medicine contains the active substance alprostadil. Alprostadil is the same as a naturally occurring chemical called prostaglandin E1. This prostaglandin can cause some types of blood vessels to widen. When Alprostadil Recordati is administered into opening at the end of the penis (urethra), this causes the penis to become rigid and erect by increasing the blood flow into its tissues.

How is this medicine used?
Alprostadil is a cream which is available in two strengths, containing a dosage of 200 or 300 micrograms alprostadil. The medicine can only be obtained with a prescription.

The cream should be applied on the tip of the penis within 5 to 30 minutes prior to attempting intercourse. Each single-dose container is for single use only. Please read section 3 of the package leaflet for step-by-step instructions on how to apply Alprostadil Recordati.

The onset of effect is within 5 to 30 minutes after administration. The duration of effect is approximately 1 to 2 hours. The actual duration can vary from patient to patient.

Detailed information on dosing recommendations and the duration of treatment are presented in section 3 of the package leaflet.

How has this medicine been studied?
The company provided data of efficacy and safety studies. The medicine Evaluation Board of the Netherlands assessed study data on almost 2500 patients. The two major questions were whether a person was able to achieve vaginal penetration and maintain an erection to ejaculation. Alprostadil Recordati was shown to be more effective than placebo (dummy treatment). Overall about 40% of the subjects who used Alprostadil Recordati experienced significant beneficial effects.

What are the possible side effects from this medicine?
The safety results of the studies indicate that serious side effects are unlikely. The safety of the cream formula was sufficiently shown. The most common side effects with Alprostadil Recordati (which affect less than 1 in 10 people) are listed below.

For the user:
- rash
- mild to moderate local aching, burning or pain and redness of the penis
- genital pruritus or discomfort
- increased erection
- penile oedema
- inflammation of the glans penis (balantitis)
- penile tingling, throbbing or numbness

For the partner:
- mild vaginal burning or inching, vaginitis

For the full list of all side effect reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
The Medicines Evaluation Board decided that the benefits of Alprostadil Recordati are greater that its risks and recommended that it be approved for use. This medicine was shown to be effective in reducing erectile dysfunction. Also the safety of this medicine was proven.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that Alprostadil Recordati 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 Alprostadil Recordati, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

The company will conduct a new study to investigate if repeated use of the cream might affect the quality of semen, as this is unknown.

Other information about this medicine
In the Netherlands the marketing authorisation for Alprostadil Recordati 2 mg/g and 3 mg/g, cream was granted on 27 July 2017.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/human/index. For more information about treatment with Alprostadil Recordati, read the package leaflet http://mri.medagencies.org/download/NL_H_3303_001_FinalPL.pdf or contact your doctor or pharmacist.

This summary was last updated in December 2017..