

Summary Public Assessment Report

**Blissel
(estriol)**

SE/H/907/01/E/02

Summary Public Assessment Report

Blissel
estriol

Vaginal gel, 50 mikrogram/g

This is a summary of the public assessment report (PAR) for Blissel. It explains how Blissel 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 Blissel.

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

What is Blissel and what is it used for?

Blissel is used for vaginal problems caused by having too little ‘oestrogen’
Shortage of oestrogens may cause the vaginal wall to become thin and dry. So sexual intercourse may become painful and you may get vaginal infections. These problems can be relieved by using medicines like Blissel which contain oestrogen. It may take several days or weeks before you notice an improvement.

Blissel is used for the treatment of vaginal dryness, which is due to lack of oestrogen after menopause.

How does Blissel work?

Blissel contains estriol, a female hormone that is identical to a hormone that your body makes naturally called oestrogen.

How is Blissel used?

The pharmaceutical form of Blissel is Vaginal gel for Vaginal use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Blissel have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Blissel is effective for the treatment of vaginal dryness, which is due to lack of oestrogen after menopause.

What are the possible side effects of Blissel?

For the full list of all side effects reported with Blissel, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Blissel approved?

It was noted that the effect of Blissel in the treatment of vaginal dryness, which is due to lack of oestrogen after menopause was significantly better than treatment with placebo in a randomized, double blind placebo controlled study. Therefore, the Medical Products Agency in Sweden decided that Blissel's benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Blissel 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 Blissel, 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.

Other information about Blissel

The full PAR for Blissel can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Blissel, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-04.