

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Ovestin 1 mg per gram Vaginal Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Vaginal cream containing 1 mg estriol in 1 g of cream.

Excipient(s) with known effect:

Cetyl alcohol and stearyl alcohol.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Vaginal cream with applicator.

*Product imported from Austria:*

Ovestin cream is a homogeneous, smooth, white to nearly white mass of creamy consistency.

## 4 CLINICAL PARTICULARS

As per PA1691/017/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1691/017/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Octyldodecanol  
Cetyl palmitate  
Glycerol  
Cetyl alcohol  
Stearyl alcohol  
Polysorbate 60  
Sorbitan stearate  
Lactic acid  
Chlorhexidine dihydrochloride  
Sodium hydroxide solution for pH adjustment  
Purified water.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister and outer carton of the product as marketed in the country of origin.

#### **6.4 Special precautions for storage**

Store below 25°C. Do not freeze.

#### **6.5 Nature and contents of container**

Ovestin Cream is filled in collapsible aluminium tubes. The tubes are provided with a screw cap.

Ovestin Cream is available in tubes of 15 g.

Each tube is packed, together with an applicator in a cardboard box.

#### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

Any unused medicinal product, the applicator or waste material should be disposed of in accordance with local requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/248/001

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 26<sup>th</sup> September 2025

### **10 DATE OF REVISION OF THE TEXT**