

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Utrogestan Vaginal 200 mg vaginal capsule, soft

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 200 mg progesterone (micronised).

Excipient(s) with known effect: soya lecithin

For a full list of excipients, see Section 6.1.

## 3 PHARMACEUTICAL FORM

Vaginal Capsule, soft

*Product imported from Greece:*

Ovoid and slightly yellow soft capsules, containing whitish oily suspension.

## 4 CLINICAL PARTICULARS

As per PA22624/001/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA22624/001/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Capsule contents:*

sunflower oil, refined

soybean lecithin

*Capsule shell:*

gelatin

glycerol

titanium dioxide (E171)

### 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

Do not store above 25°C.

Store in the original blister pack and in the original outer carton in order to protect from light.

**6.5 Nature and contents of container**

Box of 15 soft capsules in: 1 blister of 7 capsules & 1 blister of 8 PVC / Al capsules

**6.6 Special precautions for disposal and other handling**

Any unused product 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**

PPA1463/231/001

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

Date of first authorisation: 27<sup>th</sup> September 2024

**10 DATE OF REVISION OF THE TEXT**