

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Utrogestan 100 mg capsules, soft

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100 mg micronized progesterone as the active ingredient.

Excipient(s) with known effect: soybean lecithin.

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Soft capsule (capsules)

*Product imported from Greece and France:*

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

## 4 CLINICAL PARTICULARS

As per PA1054/003/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1054/003/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

sunflower oil  
soybean lecithin  
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

Blisters of 10 capsules each. It is supplied in packs of three blisters containing 30 capsules.

**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**

No special requirements

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**

PPA1463/230/001

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

Date of first authorisation: 20<sup>th</sup> September 2024

**10 DATE OF REVISION OF THE TEXT**

October 2025