

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Versatis 700 mg medicated plaster

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 cm x 14 cm plaster contains 700 mg lidocaine (equivalent to 5% w/w)

### Excipient(s) with known effect

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Propylene glycol (E1520)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Medicated plaster

*Product imported from Poland, Romania, France and Italy*

White hydrogel plaster containing adhesive material, which is applied to a non-woven polyethylene terephthalate backing embossed with "Lidocaine 5%" and covered with a polyethylene terephthalate film release liner.

## 4 CLINICAL PARTICULARS

As per PA2242/007/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2242/007/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### **Self-adhesive layer:**

glycerol

liquid sorbitol

carmellose sodium

propylene glycol (E1520)

urea

heavy kaolin

tartaric acid

gelatin

polyvinyl alcohol

aluminium glycinat

disodium edetate

methyl parahydroxybenzoate (E218)

propyl parahydroxybenzoate (E216)

polyacrylic acid

sodium polyacrylate

purified water

#### **Backing fabric:**

Polyethylene terephthalate (PET)

**Release liner:**

Polyethylene terephthalate

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

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

After first opening the sachet, the plasters must be used within 14 days.

**6.4 Special precautions for storage**

Do not refrigerate or freeze.

After first opening: Keep the sachet tightly closed.

**6.5 Nature and contents of container**

Carton containing 30 plasters packed in 6 re-sealable sachets

**6.6 Special precautions for disposal**

After use the plaster still contains active substance. After removal, the used plasters should be folded in half, adhesive side inwards so that the self-adhesive layer is not exposed, and the plaster should be discarded.

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

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/299/001

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

Date of first authorisation: 16 November 2012

**10 DATE OF REVISION OF THE TEXT**

September 2022