# 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 (5% w/w) lidocaine (50 mg lidocaine per gram adhesive base)

Excipient(s) with known effect: methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and propylene glycol.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Medicated plaster

*Product imported from 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 crystallising
Carmellose sodium
Propylene glycol (E1520)
Urea
Heavy kaolin
Tartaric acid
Gelatin
Polyvinyl alcohol
Aluminium glycinate
Disodium edetate
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Polyacrylic acid
Sodium polyacrylate
Purified water

*Backing fabric and release liner:*
Polyethylene terephthalate (PET)

### 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**

*From Italy*
Do not refrigerate or freeze.
After first opening: Keep the sachet tightly closed.

*From France*
Do not refrigerate or freeze.
After first opening: Keep the sachet tightly closed to protect from light.

**6.5 Nature and contents of container**

An over-labelled 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**

IMED Healthcare Ltd.
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Ballycoolin
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**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/135/001

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

Date of first authorisation: 17th August 2012

**10 DATE OF REVISION OF THE TEXT**

May 2022