

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Versatis 700 mg medicated plaster

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

*Product imported from Italy:*

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

*Product imported from France:*

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

Excipients 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 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.

*Product imported from France:*

The medicated plaster is 14 cm long and 10 cm wide and marked "lidocaine 5%".

## 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:**

Polyethylene terephthalate (PET)

**Release liner:**

Polyethylene terephthalate

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

The shelf –life expiry date of this product shall be the date shown on the container and outer package of the product on the market 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 to protect from light.

**6.5 Nature and contents of container**

Re-sealable sachet containing 5 plasters.

Each carton contains 10 or 30 plasters.

Not all pack sizes may be marketed.

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

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**

Merit Pharmaceuticals Limited  
Unit C4 Metropoint Business Park  
Kettles Lane  
Swords  
Co Dublin  
K67 RH92  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23080/013/001

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

Date of first authorisation: 4th July 2014

**10 DATE OF REVISION OF THE TEXT**

