Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Versatis 5% 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)

Excipients with known effect:
Methyl parahydroxybenzoate (E218) 14 mg
Propyl parahydroxybenzoate (E216) 7 mg
Propylene glycol 700 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster

Product imported from the UK 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 PA1189/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1189/009/001

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 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 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

Re-sealable sachet composed of paper/polyethylene/aluminium/ethylene meta-acrylic acid co-polymer containing 5 plasters.
Each carton contains 30 plasters.

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

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

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United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/097/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th January 2013

10 DATE OF REVISION OF THE TEXT

September 2015