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), propyl parahydroxybenzoate (E216) and propylene glycol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated plaster

Product imported from Italy:
White hydrogel patch containing adhesive material applied onto woven polyethylene terephthalate embossed with the words ”Lidocaine 5%” and covered with a protective film of polyethylene terephthalate.

4 CLINICAL PARTICULARS

As per PA1189/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1189/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Italy
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

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

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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/211/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th January 2014

10 DATE OF REVISION OF THE TEXT