

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Efudix 5 % w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Efudix cream contains:
Active substance:
5 %w/w Fluorouracil

Excipients:
Stearyl alcohol
Propylene glycol (E1520)
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the Netherlands
Smooth, white, opaque cream.

4 CLINICAL PARTICULARS

As per PA1332/032/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1332/032/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearyl alcohol
White soft paraffin
Polysorbate 60
Propylene glycol (E1520)
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Purified water

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.

Shelf life after first opening the immediate packaging: 90 days for 40g tubes.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Keep the tube tightly closed.

6.5 Nature and contents of container

Efudix cream is packed in 40g aluminium membrane-sealed tubes, coated inside with an epoxy phenolic resin derivative lacquer. The tube is closed with a polypropylene PP membranec piercing cap.

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

Efudix is for topical use only and care should be taken to avoid contact with mucous membranes or the eyes. The hands should be washed carefully after applying the cream.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/119/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th August 2014

10 DATE OF REVISION OF THE TEXT

September 2014