

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Metformin Hydrochloride 500mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml oral solution contains 500mg Metformin Hydrochloride.

1ml of oral solution contains 100mg Metformin Hydrochloride.

Excipients: Sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217) and maltitol liquid (E965)

Sodium = 5.3mg/ 5ml

Potassium = 14.5mg/ 5ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

Product imported from the United Kingdom.

Clear brown liquid.

4 CLINICAL PARTICULARS

As per PA0312/011/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0312/011/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl parahydroxybenzoate (E219),

Sodium propyl parahydroxybenzoate (E217),

Liquid maltitol (E965),

Sodium dihydrogen phosphate dihydrate,

Disodium hydrogen phosphate anhydrous (E339),

Acesulfame potassium (E950),

Ammonia caramel (E150c),

Peppermint flavour (containing propylene glycol, isopropyl alcohol and pulegone),

Peach flavour (containing propylene glycol and isopropyl alcohol),

Purified water.

6.2 Incompatibilities

Not known.

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.

6.4 Special precautions for storage

Do not store above 25°C.
Discard 28 days after first opening.

6.5 Nature and contents of container

Amber (Type III) glass bottles
Closures: HDPE, EPE wadded, tamper evident, child resistant closure
Dosing Device: 5 ml polypropylene spoon
Pack Size: 150ml

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

Any unused product or waste material should be disposed of in accordance with local requirements.

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7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/137/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th January 2015

10 DATE OF REVISION OF THE TEXT