Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zoton FasTab 15 mg oro-dispersible tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each oro-dispersible tablet contains 15mg of lansoprazole.

Excipient(s) with known effect:
Each 15 mg oro-dispersible tablet contains lactose and aspartame (E951).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oro-dispersible tablet

Product imported from UK:
White to yellowish white, circular, flat bevelled-edge oro-dispersible tablet with '15' debossed on one side.
Each oro-dispersible tablet contains orange to dark brown microgranules.

4 CLINICAL PARTICULARS

As per PA0822/101/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/101/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Magnesium carbonate
Low substituted hyprolose
Hyprolose
Hypromellose
Titanium dioxide (E171)
Talc
Mannitol

Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent
Polyacrylate dispersion 30 per cent
Macrogol 8000
Glycerol monostearate
Polysorbate 80
Triethyl citrate
Citric acid anhydrous
Crospovidone
Magnesium Stearate
Aspartame (E951)
Strawberry Flavour
Iron oxide red (E172)
Iron oxide yellow (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister strips and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25˚C.
Store in the original package in order to protect from moisture

6.5 Nature and contents of container

Aluminium blisters in an over-labelled cardboard carton containing 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex
UB5 5QS

United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th June 2010

10 DATE OF REVISION OF THE TEXT

January 2019