Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zoton FasTab 30 mg oro-dispersible tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each oro-dispersible tablet contains 30mg lansoprazole

Excipients with known effect:
Each 30 mg oro-dispersible tablet contains 30 mg of lactose and 9.0 mg of aspartame (E951).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oro-dispersible tablet
Product imported from the UK
White to yellowish white, circular, flat with a bevelled-edge oro-dispersible tablet with '30' debossed on one side.
Each oro-dispersible tablet contains orange to dark brown micro granules.

4 CLINICAL PARTICULARS

As per PA0822/101/003

4.4 Special warnings and precautions for use

As Zoton FasTab contains lactose, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Zoton contains aspartame, which is a source of phenylalanine and may be harmful to people with phenylketonuria.

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/101/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Magnesium carbonate
Low-substituted hydroxypropyl cellulose
Hydroxypropyl cellulose
Hypromellose
Titanium dioxide (E171)
Talc
Mannitol
Methacrylic acid – ethyl acrylate copolymer
Polyacrylate dispersion
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 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.
Store in the original package.

6.5 Nature and contents of container

Aluminium blisters in an overlabelled cardboard carton containing 28 tablets.

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th March 2009

Date of last renewal: 27th March 2014

10 DATE OF REVISION OF THE TEXT

July 2017