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 15mg oro-dispersible tablet contains lactose and aspartame

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oro-dispersible tablet

Products imported from the UK and Italy:
White to yellowish-white, circular, flat beveled-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
Heavy Magnesium carbonate
Low-substituted hyprolose
Hyprolose
Hypromellose
Titanium dioxide (E 171)
Talc
Mannitol
Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent
Polyacrylate dispersion 30%
Macrogol 8000
Glyceryl monosterate
Polysorbate 80
Triethyl citrate
Citric acid anhydrous
Crospovidone
Magnesium stearate
Aspartame (E951)

Strawberry flavour
Iron oxide red & 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 original package in order to protect from moisture.

6.5 Nature and contents of container

Blister packs of 28 tablets contained in an outer cardboard carton.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/058/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 February 2005

Date of last renewal: 18 February 2010

10 DATE OF REVISION OF THE TEXT

June 2018