Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zoton FasTab 30mg Oro-Dispersible Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each oro-dispersible tablet contains 30 mg of lansoprazole.

Excipient(s) with known effect
Each 30 mg oro-dispersible tablet contains lactose and aspartame (E951).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oro-Dispersible Tablet.

Product imported from the UK and Italy:
White to yellowish-white, circular, flat bevelled-edge oro-dispersible tablet with “30” debossed on one side. Each oro-dispersible tablet contains orange to dark brown microgranules.

4 CLINICAL PARTICULARS

As per PA0822/101/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/101/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Heavy magnesium carbonate
Low-substituted hyprolose
Hyprolose
Hypromellose
Titanium dioxide
Talc
Mannitol
Methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent
Polyacrylate dispersion 30 per cent
Macrogol 8000
Citric acid anhydrous
Glycerol monostearate
Polysorbate 80
Iron oxide yellow (E172)
Iron oxide red (E172)
Crospovidone
Magnesium stearate
Strawberry flavour

Aspartame (E951)
Triethyl citrate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister 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. Do not refrigerate
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Aluminium blister packs of 7 tablets packed in cartons of 28 tablets in an overlabelled outer carton.

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

Clear Pharmacy
157-173 Roden Street
Belfast
BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th August 2010

10 DATE OF REVISION OF THE TEXT

January 2017