Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zoton FasTab 15mg Oro-dispersible Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each oro-dispersible tablet contains 15mg lansoprazole.
Excipients: Lactose
Aspartame (E951)
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oro-dispersible tablet

Product imported from the UK & Italy:
White to yellowish white, circular, flat tablets with a bevelled-edge and speckled with orange to dark-brown gastro-resistant microgranules with '15' imprinted on one side and plain on the other.

or

White to yellowish white, circular, flat, bevelled-edge tablet and speckled with orange to dark brown gastro-resistant microgranules, plain on both sides.

4 CLINICAL PARTICULARS

As per PA0822/101/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/101/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

triethyl citrate
aspartame (E951)
lactose monohydrate
microcrystalline cellulose
magnesium carbonate
low-substituted hyprolose
hyprolose
hypromellose
titanium dioxide (E171)
talc
methacrylic acid – ethyl acrylate copolymer
polyacrylate dispersion
macrogol 8000
citric acid anhydrous
glycerol monostearate
polysorbate 80

crospovidone
magnesium stearate
mannitol (E421)
yellow iron oxide (E172)
red iron oxide (E172)
strawberry flavour

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 as marketed 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 a cardboard carton containing 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/003/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th November 2006

Date of last renewal: 27th November 2011

10 DATE OF REVISION OF THE TEXT

July 2018