

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 of lansoprazole.

Excipients

Product imported from the UK: Each oro-dispersible tablet contains 30mg of lactose and 9.0mg of aspartame (E951)

Product imported from Italy: Each 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 the UK and Italy.

White to yellowish-white, circular, flat bevelled-edge oro-dispersible tablet. Each oro-dispersible tablet contains orange to dark brown microgranules. Each oro-dispersible tablet is imprinted with '30' on one side and is strawberry flavoured.

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

Magnesium carbonate

Low-substituted hydroxypropyl cellulose

Hydroxypropyl cellulose

Hypromellose

Titanium dioxide

Talc

Mannitol (E421)

Methacrylic acid – ethyl acrylate copolymer

Polyacrylate dispersion

Macrogol 8000

Glyceryl monostearate

Polysorbate 80

Triethyl citrate

Citric acid anhydrous

Crospovidone

Magnesium stearate

Aspartame (E951)
Strawberry flavour
Iron oxide red and yellow (E172).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be 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.
Do not refrigerate.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th March 2008

10 DATE OF REVISION OF THE TEXT

May 2016