

# 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.

Excipients: Each tablet contains 15mg of lactose and 4.5mg of aspartame

For a 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 bevelled-edge oro-dispersible tablet. Each oro-dispersible tablet contains orange to dark brown microgranules. Each oro-dispersible tablet is imprinted with '15' on one side and is strawberry flavoured.

## 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

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 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. Do not refrigerate.

## **6.5 Nature and contents of container**

Aluminium blisters in an overlabelled 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**

PPA1463/001/001

## **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