

## 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 lansoprazole

#### Excipients with known effect:

Each 15 mg oro-dispersible tablet contains 15 mg of lactose and 4.5 mg of aspartame (E951).

For the 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 with a bevelled-edge oro-dispersible tablet with '15' debossed on one side.

Each oro-dispersible tablet contains orange to dark brown micro granules.

### 4 CLINICAL PARTICULARS

As per PA0822/101/002

#### 4.4 Special warnings and precautions for use

As Zoton FasTab contains lactose, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Zoton contains aspartame, which is a source of phenylalanine and may be harmful to people with phenylketonuria.

### 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 (E171)  
Talc  
Mannitol  
Methacrylic acid – ethyl acrylate copolymer  
Polyacrylate dispersion  
Macrogol 8000  
Glycerol monostearate

Polysorbate 80  
Triethyl citrate  
Citric acid anhydrous  
Crospovidone  
Magnesium stearate  
Aspartame (E951)  
Strawberry flavour  
Iron oxide red (E172)  
Iron oxide 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 the original package.

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

Aluminium blisters in an overlabelled cardboard carton containing 28 tablets.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

LTT Pharma Limited  
Unit 18  
Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire  
B98 0RE  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/001/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 27th March 2009

Date of last renewal: 27th March 2014

**10 DATE OF REVISION OF THE TEXT**

July 2017