

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

FROVEX 2.5 mg film-coated tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 2.5 mg of frovatriptan (as succinate monohydrate).  
Excipient(s) with known effect(s): lactose.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).

*Product imported from Greece*

Round biconvex white film-coated tablet, debossed with “m” on one side and “2.5” on the other.

### 4 CLINICAL PARTICULARS

As per PA0865/009/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0865/009/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

##### *Tablet core*

Anhydrous lactose,  
Microcrystalline cellulose  
Magnesium stearate  
Sodium starch glycollate (Type A)  
Silica, colloidal anhydrous

##### *Tablet Coat*

Opadry white:  
Titanium dioxide (E 171)  
Anhydrous lactose,  
Hypromellose (E 464)  
Macrogol 3000  
Triacetin

#### 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 and outer package of the product on the market in the country of origin.

### **6.4 Special precautions for storage**

Do not store above 30°C.  
Store in the original package in order to protect from moisture.

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

PVC/PE/ACLAR/Aluminium blister packs with 6 tablets.

### **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**

LTT Pharma Limited  
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Oxleasow Road  
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B98 0RE  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/153/001

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

Date of first authorisation: 17<sup>th</sup> of April 2015

## **10 DATE OF REVISION OF THE TEXT**

July 2018