# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINE :

LRJ

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION :

| Component name | Quantity for 100ml | Function |
|---|---|---|
| Pheniramine maleate | 0,300 g | Active Substance |
| Tetryzolin (tetrahydrozoline) hydrochloride | 0,050 g | Active Substance |
| **Other ingredients :** | | |
| Boric acid | 1,450 g | Buffer |
| Borax | 0,350 g | Buffer |
| Thiomersal | 0,010 g | Conservator |
| Sodium carboxymethylcellulose | 0,500 g | Denser |
| Water for injections | qs100 ml | Vehicle |

## 3. PHARMACEUTICAL FORM :

Bottle of 10 ml of eye drops.

## 4. CLINICAL DATA :

### 4.1. THERAPEUTIC INDICATIONS :

Conditions of irritation and congestions of the ocular conjunctiva.
Conjunctivitis of toxic and allergic origin with subacute and chronic evolution.

### 4.2. DOSAGE AND METHOD OF ADMINISTRATION :

Two drops in the conjunctival sac 2 to 4 times a day for 7 to 10 days.

### 4.3. CONTRAINDICATIONS :

The product is contraindicated in patients with hypersensitivity to any component of the specialty.

### 4.4. SPECIAL WARNINGS AND SPECIAL PRECAUTIONS OF USE :

Use with caution in narrow-angle glaucoma, in patients treated with mono-oxidase inhibitors (MAOIs), in hypertensive, arrhythmic, hyperglycaemic (diabetes) patients, and in young children (less than three years).

The product if accidentally ingested or used for a long period in excessive dose ; may determine toxicity phenomena.

### 4.5. INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS :

Other Mercurial Antiseptics, Alpha Sympathomimetics.

### 4.6. PREGNANCY AND BREASTFEEDING :

Thiomersal is contraindicated during pregnancy and breastfeeding

### 4.7. EFFECTS ON ABILITY OF DRIVING AND USING MACHINES :

Not applicable.

### 4.8. SIDE EFFECTS :

Rare cases of transitional dilation of pupils and increased intraocular pressure.

If accidentally ingested by young children: hypotonia, deep sleep, note that these systemic effects are never reported during ophthalmic use in the proportion of recommended doses.

### 4.9. OVERDOSAGE :

If the product is accidentally ingested or taken for a long term at excessive dose it may determine the toxicity phenomena.

## 5. PHARMACOLOGIC PROPERTIES :

### 5.1. PHARMACODYNAMIC PROPERTIES :

Antiallergic and ophthalmic decongestant.

## 6. PHARMACEUTICAL DATA :

### 6.1. INCOMPATIBILITIES :

Not applicable.

### 6.2. STORAGE PERIOD :

24 months from the date of manufacturing.

### 6.3. SPECIAL PRECAUTIONS OF STORAGE :

Keep away from light and heat.

Any opened bottle must be used within 15 days.

Do not store above 30°C.

**6.4. NATURE AND CONTENT OF THE OUTER PACKAGING :**

Box of a low-density, neutral polyethylene bottle with dropper and tamper-proof caps.

**7. MARKETING AUTHORIZATION HOLDER :**

Les Laboratoires Médis
Route de Tunis Km 7, 8000 Nabeul BP 206, Tunisie.

**8. PRESCRIPTION AND SUPPLY CONDITIONS :**

List I.

**9. WHAT LRJ LOOKS LIKE AND ADMINISTRATIVE IDENTIFICATION NUMBER :**

***LRJ,*** *eye drops Bottle of 10 ml.*

**Country of origin AMM N°:** 9233191

**10. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION**

AMM Date obtained: 04/04/2002

First AMM renewal date: 04/04/2007

Second AMM renewal date: 04/04/2012

Third AMM renewal date: 04/04/2017