Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ixprim 37.5 mg/325 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.

Excipients: One film coated tablet contains 1.878 mg lactose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
Pale yellow film-coated tablet, marked with the manufacturers logo ♎ on one side and ‘T5’ on the other side.

4 CLINICAL PARTICULARS

As per PA1189/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1189/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powdered cellulose
Pregelatinised starch (potato, corn and rice)
Sodium starch glycolate (potato) (type A)
Maize starch
Magnesium stearate
Hypromellose
Lactose monohydrate
Titanium dioxide (E171)
Macrogol 6000
Yellow iron oxide (E172)
Propylene glycol
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Ixprim tablets are packed in paper/PET/aluminium-PVC blisters.
Box of 60 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

PPA1562/121/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th July 2014

10 DATE OF REVISION OF THE TEXT

January 2015