# 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 with known effect: contains lactose.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from The United Kingdom*

Pale yellow film-coated tablet, marked with the manufacturer's 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

Tablet core:
powdered cellulose,
pregelatinised starch,
sodium starch glycolate (type A),
maize starch,
magnesium stearate.

Film-coating:
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 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

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

Lexon (UK) Ltd
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

# 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/010/001

# 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 2017

# 10 DATE OF REVISION OF THE TEXT