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.

Excipient with known effect: lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
Product imported from the United Kingdom and Spain:
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

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 of this product is the date shown on the blister foil 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

Blister packs of 60 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10
Ashbourne Business Park,
Rath,
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/282/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

The date of first authorisation: 19th August 2011

10 DATE OF REVISION OF THE TEXT

January 2015