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 also contains lactose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
Product imported from Spain.
Pale yellow film-coated tablet, marked with the manufacturer's logo Ω 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 (E 171)
macrogol 6000
yellow iron oxide (E 172)
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 and outer carton of the product as marketed 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/aluminium/plastic blisters.
Box of 20 and 60 tablets
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex
UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/044/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2016

10 DATE OF REVISION OF THE TEXT