

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Meloxicam 15mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 15mg meloxicam.

Excipients: contains lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK

Light yellow, round, biconvex bevel-edged tablets with “B” and “19” debossed on either side of the breakline on one side and plain on the reverse.

4 CLINICAL PARTICULARS

As per PA1063/020/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA1063/020/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate
Lactose monohydrate
Microcrystalline cellulose
Crospovidone
Colloidal anhydrous silica
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container label and outer cardboard carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

This product does not require any special storage conditions

6.5 Nature and contents of container

Blister packs of 30 tablets contained in a cardboard carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/041/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th May 2011

10 DATE OF REVISION OF THE TEXT

May 2015