Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arthrotec 75 modified-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet consists of a gastro-resistant core containing 75 mg diclofenac sodium surrounded by an outer mantle containing 200 micrograms misoprostol.

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified-release tablet.

Product imported from France
White, round, biconvex tablets marked 'SEARLE' over ‘1421’ on one side, and four times ‘A’ around the circumference with ‘75’ in the centre on the reverse side.

4 CLINICAL PARTICULARS

As per PA0822/112/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/112/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Maize starch
Povidone K-30
Magnesium stearate
Copolymer, methylacrylic acid, ethyl acrylate (1:1) (EUDRAGIT L 100-55)
Sodium hydroxide
Talc
Triethyl citrate
Hypromellose
Crospovidone
Silica colloidal anhydrous
Hydrogenated castor oil

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

Do not store above 25 °C. Store in the original package.

6.5 Nature and contents of container

The tablets are packed in blister strips and supplied in boxes of 60 tablets.

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

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/179/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT