Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arthrotec 50 modified-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet consists of a gastro-resistant core containing 50 milligrams diclofenac sodium surrounded by an outer mantle containing 200 micrograms misoprostol.

Excipient(s) with known effect: Each tablet contains lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified-release tablet

Product imported from Spain, Netherlands and France:
White, round, biconvex tablets marked 'Searle' and '1411' on one side and four 'A's on the other side.

4 CLINICAL PARTICULARS

As per PA0822/112/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/112/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Microcrystalline cellulose
Maize starch
Povidone
Cellulose acetate phthalate
Diethyl phthalate
Hypromellose
Crospovidone
Magnesium stearate
Hydrogenated castor oil
Colloidal anhydrous silica

The product imported from France contains the following excipients:
Lactose
Microcrystalline cellulose
Maize starch
Povidone
Magnesium stearate
Methacrylic acid copolymer type C
Sodium Hydroxide
Talc
Triethyl citrate
Crospovidone
Colloidal anhydrous silica

Hydrogenated castor oil

The product imported from Netherlands contains the following excipients:
Lactose monohydrate
Microcrystalline cellulose
Maize starch
Povidone K-30
Hypromellose
Crospovidone
Magnesium Stearate
Methylacrylic acid copolymer type-C
Sodium hydroxide
Talc
Triethyl citrate
Hydrogenated castor oil
Colloidal silicon dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container 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 in order to protect from moisture.

6.5 Nature and contents of container

Blister pack containing 40 or 60 tablets.
Not all pack sizes may be marketed.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/114/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 2004

Date of last authorisation: 31st March 2009

10 DATE OF REVISION OF THE TEXT

September 2024