

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arthrotec 50 modified-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg diclofenac sodium and 200 micrograms misoprostol.

Excipient(s) with known effect

Lactose monohydrate and hydrogenated castor oil

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 with 4 'A's on one side, and 'SEARLE 1411' on the other side.

4 CLINICAL PARTICULARS

As per PA0822/112/001

4.4 Special warnings and precautions for use

Contains hydrogenated castor oil. May cause stomach upset and diarrhoea.

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/112/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
microcrystalline cellulose
maize starch
povidone K30
magnesium stearate
copolymer of methacrylic acid and ethyl acrylate (1:1) (EUDRAGIT L 100-55)
sodium hydroxide
talc
triethyl citrate
hypromellose
crospovidone
colloidal anhydrous silica
hydrogenated castor oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strip and outer carton of the product as marked 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

Cardboard outer carton containing blister strip.

Pack size: 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/199/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th May 2015

10 DATE OF REVISION OF THE TEXT

June 2018