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:
Each tablet contains lactose monohydrate.
Each tablet contains hydrogenated castor oil.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified-release tablet.

Product imported from *Portugal*
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

Core:
Lactose monohydrate
Microcrystalline cellulose
Maize starch
Povidone K-30
Magnesium stearate

Mantle/Coat:
Methylacrylic acid copolymer type C
Sodium hydroxide
Talc
Triethylcitrate
Hypromellose
Crospovidone
Hydrogenated castor oil
Colloidal silicon dioxide
Microcrystalline cellulose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be 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.

6.5 Nature and contents of container

Arthrotec 75 is presented in cold-formed aluminium blisters in pack sizes 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/159/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd April 2021

10 DATE OF REVISION OF THE TEXT

July 2023