

# 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

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Modified-release tablets

*Product imported from Italy (Misofenac & Arthrotec):*

White, round, biconvex tablets, plain on both sides or white, round, biconvex tablets marked 'SEARLE' and '1421' on one side with four 'A's and '75' on the other 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  
Microcrystalline cellulose  
Maize starch  
Povidone K-30  
Methacrylic Acid Copolymer Type C  
Sodium Hydroxide  
Triethyl Citrate  
Hypromellose  
Crospovidone  
Magnesium stearate  
Hydrogenated castor oil  
Colloidal anhydrous silica.  
Talc

### 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 30 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**

PPA0465/114/002

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 31<sup>st</sup> March 2004

Date of last renewal: 31<sup>st</sup> March 2009

## **10 DATE OF REVISION OF THE TEXT**

December 2022