# SUMMARY OF PRODUCT CHARACTERISTICS

# 1 NAME OF THE MEDICINAL PRODUCT

# 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

# 3 PHARMACEUTICAL FORM

# 4 CLINICAL PARTICULARS

## 4.1 Therapeutic indications

## 4.2 Posology and method of administration

## 4.3 Contraindications

## 4.4 Special warnings and precautions for use

## 4.5 Interaction with other medicinal products and other forms of interaction

## 4.6 Fertility, pregnancy and lactation

## 4.7 Effects on ability to drive and use machines

## 4.8 Undesirable effects

## 4.9 Overdose

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

## 5.2 Pharmacokinetic properties

## 5.3 Preclinical safety data

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

## 6.2 Incompatibilities

## 6.3 Shelf life

## 6.4 Special precautions for storage

## 6.5 Nature and contents of container

## 6.6 Special precautions for disposal

# 7 MARKETING AUTHORISATION HOLDER

# 8 MARKETING AUTHORISATION NUMBER(S)

# 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

# 10 DATE OF REVISION OF THE TEXT