

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tavanic 500 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet of Tavanic 500 mg contains 500mg of levofloxacin as levofloxacin hemihydrate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Italy and Greece

Score line pale yellowish-white to reddish-white film-coated tablets. The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA0540/077/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/077/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Crospovidone
Hypromellose
Microcrystalline cellulose
Sodium stearyl fumarate

Tablet coating:

Hypromellose
Titanium dioxide E171
Talc
Macrogol
Yellow ferric oxide E172
Red ferric oxide E172

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/Aluminium blisters containing film-coated tablets.

Pack sizes for 500 mg tablets: 10

6.6 Special precautions for disposal

A score line allows adaptation of the dose in patients with impaired renal function.

As for all medicines, any unused medicinal product should be disposed of accordingly and in compliance with local environmental regulations.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/302/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th January 2013

10 DATE OF REVISION OF THE TEXT

April 2023