

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 500 mg of levofloxacin as levofloxacin hemihydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Hungary

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 E 171

Talc

Macrogol

Yellow ferric oxide E 172

Red ferric oxide E 172

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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: 5 or 10.

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

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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/190/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th January 2017

10 DATE OF REVISION OF THE TEXT