

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Avelox 400mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 film-coated tablet contains 400 mg moxifloxacin (as hydrochloride).

Excipient with known effect: contains lactose monohydrate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the Portugal.

Dull red film-coated tablet with an oblong, convex shape with facet, a dimension of 17 x 7 mm, and marked with “M400” on one side and “BAYER” on the other side.

4 CLINICAL PARTICULARS

As per PA1410/27/1

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/27/1

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
microcrystalline cellulose,
croscarmellose sodium,
lactose monohydrate,
magnesium stearate.

Coating:
hypromellose,
macrogol 4000,
iron oxide (E172),
titanium dioxide (E171).

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

Do not store above 25°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Cartons containing colourless polypropylene/aluminium blisters: The film-coated tablets are available in packs of 5.

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 MARKETING AUTHORISATION HOLDER

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/158/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st July 2015

10 DATE OF REVISION OF THE TEXT