Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Avelox 400 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 film-coated tablet contains 400 mg moxifloxacin (as hydrochloride).
Excipient with known effect: The film-coated tablet contains lactose monohydrate (see section 4.4).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from United Kingdom, Portugal and Greece:
Dull red film-coated tablet tablet with an oblong, convex shape with facet, and marked with "M400" on one side and "BAYER" on the other side.

4 CLINICAL PARTICULARS

As per PA1410/027/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/027/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Microcrystalline cellulose
Croscarmellose sodium
Lactose monohydrate
Magnesium stearate

Film coat:
Hypromellose
Macrogol 4000
Iron oxide (E172)
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 or white opaque polypropylene/aluminium blisters:
The film-coated tablets are available in packs of 5 tablets.

6.6 Special precautions for disposal and other handling

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

PPA0465/230/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th July 2009

10 DATE OF REVISION OF THE TEXT

March 2020