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 moxifoxacin (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 Greece
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 PA1410/027/001

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
Ferric oxide (E172)
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister pack and outer packaging of the product as marketed 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 film-coated tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/118/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th March 2018

10 DATE OF REVISION OF THE TEXT

May 2018