Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minocin SA 100 mg Modified Release Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100mg of minocycline equivalent to 116 mg of minocycline hydrochloride dihydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified release hard capsules

Product imported from the UK:
Two piece, hard shell, size 2 capsule with an orange opaque body and a brown cap containing a mixture of off white and coloured (yellow, green, brown/black) spherical pellets.

4 CLINICAL PARTICULARS

As per PA2010/060/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/060/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Croscarmellose sodium
Hypromellose phthalate 50
Hypromellose
Light liquid paraffin
Opaspray White K-1-7000
(Containing titanium dioxide E171 and hydroxypropylcellulose)

Capsule body:
Titanium dioxide (E171)
Iron oxide yellow (E172)
Iron oxide red (E172)
Gelatin

Capsule cap:
Titanium dioxide (E171)
Red iron oxide (E172)
Black iron oxide (E172)
Yellow iron oxide (E172)
Gelatin

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

Do not store above 25°C. Store in the original package.
Keep the container in the outer carton.

6.5 Nature and contents of container

PVC/PVDC aluminium blister packs containing 56 capsules.

6.6 Special precautions for disposal

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

PPA1463/097/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th July 2014

10 DATE OF REVISION OF THE TEXT

September 2019