

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benetor 10 mg Film-coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mg tablet contains 10 mg of olmesartan medoxomil
Excipients: Also contains lactose monohydrate (see section 4.4)
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from France:

White, circular, film-coated tablets with C13 embossed on one side.

4 CLINICAL PARTICULARS

As per PA1595/001/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA1595/001/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Cellulose, microcrystalline
Lactose monohydrate
Hydroxypropylcellulose
Low substituted hydroxypropylcellulose
Magnesium stearate

Tablet coat:

Titanium dioxide (E 171)
Talc
Hypromellose

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium blister pack.
Packs of 30 film-coated tablets.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4, Bradfield Road
Ruislip
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HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/151/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th July 2011

10 DATE OF REVISION OF THE TEXT

April 2015