

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Inspra 25mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25mg eplerenone.
Excipient(s): lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Poland

Yellow tablet with stylized "Pfizer" on one side of the tablet, "NSR" over "25" on the other side of the tablet.

Product imported from Spain:

Yellow tablet marked with 'NSR' over '25' on one side of the tablet and plain on the reverse.

4 CLINICAL PARTICULARS

As per PA0822/020/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/020/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core

Lactose monohydrate
Microcrystalline cellulose (E460)
Croscarmellose sodium (E468)
Hypromellose (E464)
Sodium laurilsulfate
Talc (E553b)
Magnesium stearate (E470b)

Tablet coating

Opadry yellow:
Hypromellose (E464)
Titanium dioxide (E171)
Macrogol 400
Polysorbate 80 (E433)
Iron oxide yellow (E172)
Iron oxide red (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed 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

Over-labelled cardboard carton containing 3 blister strips (10 tablets per strip).
Pack size: 30 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/132/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th November 2009

10 DATE OF REVISION OF THE TEXT

November 2015