

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Inspira 50mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of eplerenone.

Excipients with known effect: lactose monohydrate

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Poland and Italy

Yellow tablet with stylized “Pfizer” on one side of tablet, “NSR” over “50” on the other side of tablet.

4 CLINICAL PARTICULARS

As per PA0822/020/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/020/002

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 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

Opaque PVC/Al blisters containing 30 tablets

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/297/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th October 2012

10 DATE OF REVISION OF THE TEXT

August 2016