

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Inspira 25mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25 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 “25” on the other side of tablet.

## 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 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**

PPA0465/297/001

## **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