Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Alendronic Acid 70 mg Tablets Once Weekly

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 70 mg alendronic acid (as alendronate sodium monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK

White to off-white, flat-faced bevel-edged round tablet, debossed with T on one side, plain on the other side.

4 CLINICAL PARTICULARS

As per PA0749/016/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/016/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose (E460)
Croscarmellose sodium
Magnesium Stearate

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

Blister pack of 4 tablets contained in a carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/058/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th May 2015

10 DATE OF REVISION OF THE TEXT

February 2018