Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Actonel Once a week 35mg Film-coated tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 35 mg risedronate sodium, (equivalent to 32.5 mg risedronic acid).

Excipients with known effect: Each film-coated tablet contains lactose.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film coated tablet.

Product imported from Italy, Spain, Greece, the UK and France:
Oval, light-orange tablet with 'RSN' engraved one side and '35 mg' on the other.

4 CLINICAL PARTICULARS

As per PA1390/193/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1390/193/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Microcrystalline cellulose
Crospovidone
Magnesium stearate

Film coating:
Dri-Klear (hypromellose, macrogol 400, hyprolose macrogol 400, macrogol 8000 and colloidal hydrated silica)
Chroma-Tone White DDB-7536W (titanium dioxide (E171), hypromellose)
Ferric oxide yellow (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 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 packs of 4 tablets contained in an outer cardboard carton.

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/165/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 November 2005
Date of last renewal: 04 November 2010

10 DATE OF REVISION OF THE TEXT

December 2018