

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 35mg risedronate sodium (equivalent to 32.5mg risedronic acid)

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from the UK:

Oval, light-orange, film-coated tablet with RSN on one side and 35mg on the other

4 CLINICAL PARTICULARS

As per PA1635/001/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1635/001/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:

Lactose monohydrate

Cellulose microcrystalline

Crospovidone

Magnesium stearate

Film Coating:

Iron oxide yellow (E172)

Iron oxide red (E172)

Hypromellose

Macrogol

Hyprolose

Silicon dioxide

Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

Clear PVC/aluminium foil blister in an over-labelled cardboard carton containing 4 tablets.

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Ltd.
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th April 2010

10 DATE OF REVISION OF THE TEXT

February 2017