Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Actonel Plus Ca & D 35 mg + 1000 mg / 880 IU film-coated tablets + effervescent granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 35 mg risedronate sodium, (equivalent to 32.5 mg risedronic acid).
Each sachet of effervescent granules contains 2500 mg calcium carbonate equivalent to 1000 mg calcium and 22 micrograms (880 IU) colecalciferol (vitamin D_3).

Excipients: Each film-coated tablet contains lactose. Each sachet of effervescent granules contains potassium (163 mg), sucrose, soya-bean oil and sorbitol.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

Effervescent granules
Calcium carbonate/colecalciferol, white effervescent granules.

4 CLINICAL PARTICULARS

As per PA1635/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1635/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Film-coated tablet:
Tablet core: Lactose monohydrate
Cellulose microcrystalline
Crospovidone A
Magnesium stearate
Film coating: Hypromellose
Macrogol
Hyprolose
Silicon dioxide
Titanium dioxide (E171)
Iron oxide yellow (E172)
Iron oxide red (E172)

Effervescent granules:
Citric acid anhydrous
Malic acid
Gluconolactone
Maltodextrin

Sodium cyclamate
Saccharin sodium
Sorbitol E420
Mannitol E421
Gluconolactone
Dextrin, acacia
Lemon oils
Lime flavour
Rice starch
Potassium carbonate
All-rac--Tocopherol
Soya-bean oil, hydrogenated
Gelatin
Sucrose
Maize starch

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

Combination pack constituted of an outer carton pack containing weekly unit(s) (carton boxes).
Each weekly unit contains:
Clear PVC/aluminium foil blister containing one tablet
Six sachets (laminated aluminium paper foil) containing effervescent granules

Pack sizes:
4 weekly units: 4x(1 film-coated tablet + effervescent granules in 6 sachets)
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/090/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 17th April 2009

10 DATE OF REVISION OF THE TEXT

November 2014