

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Actonel Plus Ca & D 35 mg film-coated tablets + 1000 mg/880 IU 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 1000 mg calcium (as 2500 mg calcium carbonate) and 22 micrograms (880 IU) colecalciferol (vitamin D₃).

Excipients with known effect:

Each film-coated tablet contains lactose monohydrate.

Each sachet of effervescent granules contains potassium, sucrose, soya-bean oil and sorbitol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from France:

Film-coated tablet

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

Effervescent granules

White effervescent granules.

4 CLINICAL PARTICULARS

As per PA22668/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22668/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Film-coated tablet:

Tablet core:

Lactose monohydrate,

Crospovidone A,

Magnesium stearate.

Cellulose microcrystalline,

Film coating:

Hypromellose,

Macrogol

Hydroxypropylcellulose

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)
Dextrin,
Acacia
Natural Lemon oils
Natural Lime flavour
Rice starch,
Potassium carbonate
All-rac- α -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 shall be the date shown on the blister, sachet 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

The medicine is supplied as a combination product containing tablets and sachets.

Each monthly unit contains:

Clear PVC/aluminium foil blister containing four tablets

Twenty-four sachets (laminated aluminium paper foil) containing effervescent granules

Pack size: 1 monthly unit 1 x (4 film coated tablets + effervescent granules in 24 sachets)

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
30 August 2022

Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/305/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th March 2013

10 DATE OF REVISION OF THE TEXT

August 2022