

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Binosto Once Weekly 70 mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains 70 mg alendronic acid as 91.37mg of alendronate sodium trihydrate.
Excipients: each effervescent tablet contains 602.54 of sodium.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablet

Product imported from Spain

White to off-white round effervescent tablets of 25 mm diameter, flat faced with bevelled edges. After dissolution the solution has a pH of 4.8 – 5.4. The appearance of the product after dissolution is a clear colourless solution.

4 CLINICAL PARTICULARS

As per PA0126/280/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0126/280/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen citrate

Citric acid anhydrous

Sodium hydrogen carbonate

Sodium carbonate anhydrous

Strawberry flavour [Maltodextrin (Maize), Arabic gum, Propylene glycol (E 1520), nature-identical flavouring substances]

Acesulfame potassium

Sucralose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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 temperature storage conditions.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

The effervescent tablets are provided in strips of composite foil, with 2 effervescent tablets packed in individual units per strip.

Pack with 4 effervescent tablets.

6.6 Special precautions for disposal and other handling

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

Lexon (UK) Ltd
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United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/045/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th April 2018

10 DATE OF REVISION OF THE TEXT