Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fosamax Once Weekly 70 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains the equivalent of 70 mg of alendronic acid as 91.37 mg alendronate sodium trihydrate.

Excipients: Lactose anhydrous

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK, France, Italy and the Netherlands:
Oval white tablets, marked with an outline of a bone image on one side, and '31' on the other.

4 CLINICAL PARTICULARS

As per PA1286/008/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/008/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose (E460)
Lactose anhydrous
Croscarmellose sodium
Magnesium stearate (E572)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

Aluminium blisters in a cardboard carton containing 4 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 September 2006

Date of last renewal: 22 September 2011

10 DATE OF REVISION OF THE TEXT

November 2015