

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TOBI 300 mg/5 ml Nebuliser Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ampoule of 5ml contains tobramycin 300mg as a single dose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nebuliser solution.

Product imported from the UK:

Clear, slightly yellow solution.

4 CLINICAL PARTICULARS

As per PA 0013/123/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 0013/123/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium chloride
- Water for injections
- Sulphuric acid (for pH adjustment)
- Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

In the absence of compatibilities studies, this medicinal product must not be mixed with any other medicinal product in the nebuliser.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer packaging of the product on the market in the country of origin.

For single use. The contents of the whole ampoule should be used immediately after opening (see section 6.6). Discard any remaining contents.

6.4 Special precautions for storage

Store at 2-8° C in a refrigerator. Store in the original package in order to protect from light.

After removal from the refrigerator, or if refrigeration is unavailable, TOBI pouches (intact or opened) may be stored at up to 25° C for up to 28 days.

TOBI solution is normally slightly yellow, but some variability in colour may be observed, which does not indicate loss of activity if the product has been stored as recommended.

6.5 Nature and contents of container

TOBI is supplied in 5ml single-use ampoules. One outer carton contains a total of 56 ampoules comprising of 4 sealed foil pouches. Each pouch contains 14 ampoules packed in a plastic tray.

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

TOBI is a sterile, non-pyrogenic, aqueous preparation for single use only. As it is preservative-free, the contents of the whole ampoule should be used immediately after opening and any unused solution discarded. Opened ampoules should never be stored for re-use.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
157-173 Roden Street
Belfast BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1596/056/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th October 2011

10 DATE OF REVISION OF THE TEXT

November 2014