

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Ventolin Nebules 2.5mg / 2.5ml nebuliser solution.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The concentration of salbutamol is 0.1%

Each nebule contains 2.5 mg Salbutamol (as sulphate).

Each ml of solution contains 1 mg Salbutamol (as sulphate).

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Nebuliser Solution.

*Product imported from the UK:*

A clear colourless to pale yellow, sterile, isotonic, aqueous nebuliser solution

### 4 CLINICAL PARTICULARS

As per PA1077/049/005

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/049/005

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Sodium chloride

Dilute sulphuric acid

Water for Injections

#### 6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

#### 6.3 Shelf life

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

After opening of foil packaging: 3 months.

Once nebule is opened, use immediately.

## **6.4 Special precautions for storage**

Do not store above 30°C

Keep nebules in the outer carton.

The nebules should be protected from light after removal from the foil tray.

## **6.5 Nature and contents of container**

The nebules consist of low-density polyethylene (LDPE). Five nebules are linked together in a strip. Each strip of five nebules is packaged in a laminated aluminium foil blister pack consisting of a base foil bay and foil lidding material. Ventolin Nebules are available in packs of 20 nebules.

## **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**

*Dilution:* Ventolin Nebules may be diluted with sterile normal saline.

Do not use the product if discoloured.

Any unused solution in the chamber for the nebuliser must be discarded.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1328/041/002

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of First Authorisation: 18 August 2006

Date of Last Renewal: 18 August 2011

## **10 DATE OF REVISION OF THE TEXT**

June 2015