

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Salamol CFC-Free Inhaler 100 micrograms Pressurised Inhalation, Suspension

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains salbutamol sulphate equivalent to 100 micrograms salbutamol.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension

*Product imported from the UK:*

Pressurised container fitted with a metering valve.

### 4 CLINICAL PARTICULARS

As per PA0436/032/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0436/032/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Ethanol, anhydrous  
Norflurane (Propellant HFA-134a)

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed in the country of origin.

#### 6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Protect from frost, direct sunlight and heat.  
The canister contains a pressurized liquid. Do not expose to temperatures higher than 50°C.  
Do not pierce, break or burn the canister even when apparently empty.

#### 6.5 Nature and contents of container

A pressurised aluminium container with a metering valve and actuator. Each pack contains a single inhaler which supplies 200 metered doses.

**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.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1328/040/001

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

Date of first authorisation: 4th August 2006

Date of last renewal: 4th August 2011

**10 DATE OF REVISION OF THE TEXT**

November 2015