

# 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 actuation contains salbutamol sulphate equivalent to 100 micrograms salbutamol per metered dose. 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 pressurised liquid. Do not expose to temperatures higher than 50°C.

Do not puncture, break or burn the canister even when apparently empty.

As with most inhaled medication in aerosol canisters, the therapeutic effect of this medication may decrease when the canister is cold.

### 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**

Any unused product or waste material should be disposed in accordance with local requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA 1151/74/1

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

Date of First Authorisation: 20th June 2008

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

November 2014