

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Actifed 60mg/2.5mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 60mg pseudoephedrine hydrochloride and 2.5mg triprolidine hydrochloride.

Excipient with known effect: contains lactose.

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from the UK*

White, round biconvex tablets with a score line and marked M2A on one side and plain on the other.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

## 4 CLINICAL PARTICULARS

As per PA0330/049/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0330/049/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose  
Maize starch  
Povidone  
Magnesium stearate

### 6.2 Incompatibilities

Not applicable.

### 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.

### 6.4 Special precautions for storage

Do not store above 25°C  
Store in original container to protect from moisture and light

### 6.5 Nature and contents of container

Over-labelled cardboard outer containing 1 blister strip.  
Pack size: 12 tablets.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

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

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/210/001

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

Date of first authorisation: 7<sup>th</sup> February 2014

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

May 2019