

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Molaxole powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains following active substances

Macrogol 3350	13.125 g
Sodium chloride	350.7 mg
Potassium chloride	46.6 mg
Sodium hydrogen carbonate	178.5 mg

The content of electrolyte ions per sachet when made up to 125 ml of solution

Sodium	65 mmol/l
Potassium	5.4 mmol/l
Chloride	53 mmol/l
Hydrogen carbonate	17 mmol/l

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution

Product imported from the UK

A white crystalline powder.

4 CLINICAL PARTICULARS

As per PA1332/038/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1332/038/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfam potassium (E950)

Lemon flavour

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.

Store the reconstituted solution in refrigerator (2°C-8°C) and discard any solution not used within 6 hours.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture. For storage conditions after reconstitution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Sachets of Paper/LDPE/Aluminium/LDPE

Package of: 30 sachets

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/034/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th November 2013

10 DATE OF REVISION OF THE TEXT

January 2018