

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

RISPERDAL 1 mg/ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml oral solution contains 1 mg of risperidone.

Excipient with known effect

Benzoic acid (E210)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

Product imported from Germany

The solution is clear and colourless.

4 CLINICAL PARTICULARS

As per PA0748/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartaric Acid (E334)

Benzoic Acid (E210)

Sodium Hydroxide

Purified Water

6.2 Incompatibilities

Incompatible with most types of tea including black tea.

6.3 Shelf life

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

Shelf life after first opening: 3 months

6.4 Special precautions for storage

Do not store above 30 °C.

Do not refrigerate or freeze.

6.5 Nature and contents of container

Amber glass bottle with a plastic child-resistant cap. RISPERDAL oral solution is presented in bottle size of 100 ml. A dosing pipette is also provided.

The pipette supplied with the bottle size of 100 ml is graduated in milligrams and millilitres with a minimum volume of 0.25 ml and a maximum volume of 3 ml.

Graduation marks in 0.25 ml (equals 0.25 mg oral solution) increments up to 3 ml (equals 3 ml oral solution) are printed on this pipette.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.

Joop Geesinkeweg 901

1114 AB Amsterdam-Duivendrecht

Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st December 2018

10 DATE OF REVISION OF THE TEXT