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:
1 ml oral solution contains 2 mg benzoic acid

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

The oral solution is clear and colourless.

Product imported from Germany:

4 CLINICAL PARTICULARS

As per PA22612/010/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/010/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartaric acid
Benzoic acid
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 of this product is the date shown on the bottle and outer package of the product 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 (polypropylene) child-resistant and tamper-evident cap. RISPERDAL oral solution is presented in bottle sizes 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 mg oral solution) are printed on this pipette.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/525/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st May 2026

10 DATE OF REVISION OF THE TEXT