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

Excipients with known effect
1 ml oral solution contains 2 mg benzoic acid (E 210)
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from Germany:
The oral solution is clear and colourless.

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 (E334)
Benzoic acid (E 210)
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 shall be the date shown on the container and outer package of the product as marketed 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 child-resistant 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. The pipette supplied with the bottle size of 120 ml is graduated in milligrams and millilitres with a minimum volume of 0.25 ml and a maximum volume of 4 ml. Graduation marks in 0.25 ml (equals 0.25 mg oral solution) increments up to 4 ml (equals 4 mg 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

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue,
Northwest Business Park,
Ballycoolin,
Dublin 15,
Ireland.

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/227/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th May 2024

10 DATE OF REVISION OF THE TEXT