Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Citidaron 1.5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.5 mg of cytisinicline (previously used name: cytisine).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Product imported from Poland.
Round, biconvex, white tablet with diameter 6 mm.

4 CLINICAL PARTICULARS

As per PA22714/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22714/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Cellulose, microcrystalline
Magnesium stearate
Glycerol dibehenate
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store below 25°C.
Store in the original package in order to protect from moisture and light.

6.5 Nature and contents of container

PVC/PCTFE/Aluminium or PVC/PE/PVDC/Aluminium blisters placed into cardboard box containing 100 tablets.

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

Originalis B.V.
Diamantweg 4
1812 RC Alkmaar
The Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/041/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th July 2026

10 DATE OF REVISION OF THE TEXT

September 2026