

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cariban 10 mg/10 mg modified-release hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

doxylamine succinate..... 10 mg

pyridoxine hydrochloride..... 10 mg

Excipient with known effect: Sucrose (79.5 mg per capsule).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Modified-release hard capsule.

Product imported from Belgium, Italy and Greece

Green capsule, size 3, containing two types of modified-release pellets one for each active ingredient, one containing Pyridoxine hydrochloride and the other containing Doxylamine succinate.

4 CLINICAL PARTICULARS

As per PA1776/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1776/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

sucrose
corn starch
shellac
povidone
talc
methacrylic acid - methyl methacrylate copolymer (1:1)
silica colloidal anhydrous

Hard gelatine capsule:

gelatine
indigo carmine (E132)
quinoline yellow (E104)
titanium dioxide (E171)

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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Cartons containing: 24 hard capsules in 2 PVC/PVdC-Aluminium blisters, with 12 capsules in each blister.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
Amsterdam-Duivendrecht
Noord-Holland
1114 AB
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th September 2025

10 DATE OF REVISION OF THE TEXT