Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zanaflex 4 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4 mg of tizanidine (as hydrochloride).

Excipient(s) with known effect
Each tablet contains lactose, anhydrous.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from Germany:

White to off-white, biconvex, round, tablets, 9 mm in diameter, debossed "T4" on one side and quadrisected by score lines on the other.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0749/054/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/054/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Cellulose, microcrystalline
Stearic acid
Silica, colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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 30 °C.

6.5 Nature and contents of container

Blister PVC/PVDC/Aluminium.
Blister packs of 120 tablets in outer carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/474/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st May 2021

10 DATE OF REVISION OF THE TEXT

November 2022