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.
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 score line 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
Silica, colloidal anhydrous
Stearic acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed 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

6.6 Special precautions for disposal

No special 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

PPA1463/224/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th May 2024

10 DATE OF REVISION OF THE TEXT