Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zanaflex 4mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient with known effect: Each tablet contains lactose anhydrous.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.

Product imported from the Netherlands:
White, circular, flat tablets, cross-scored on one side and engraved with R L on the other side.

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

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package.

6.5 Nature and contents of container

Blister packs of 30 tablets contained in an outer cardboard carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/168/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 February 2006

Date of last renewal: 10 February 2011

10 DATE OF REVISION OF THE TEXT

February 2017