

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zyban 150 mg prolonged release tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains bupropion hydrochloride 150 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release tablet.

Product imported from Greece

White, film-coated, biconvex, round tablet printed on one side with GX CH7 and plain on the other side.

4 CLINICAL PARTICULARS

As per PA1077/017/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/017/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Microcrystalline cellulose

Hypromellose

Cysteine hydrochloride monohydrate

Magnesium stearate

Film coat:

Hypromellose

Macrogol 400

Titanium dioxide (E171)

Carnauba wax

Printing ink:

Iron oxide black (E172)

Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be 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

Carton containing foil / foil child-resistant blister strips - 100 tablets per pack. Each blister strip contains 10 tablets.

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/089/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th September 2017

10 DATE OF REVISION OF THE TEXT