Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zyban 150 mg prolonged release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 150 mg bupropion hydrochloride.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release tablet.

Product imported from Romania and Belgium.
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 coating:
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 for 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 25 °C. Store in the original package.

6.5 Nature and contents of container

PA-Alu-PVC/Paper – Alu blisters.
They are available in cartons containing blisters of 100 tablets (10 blisters of 10 tablets each).

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PPA2306/005/001

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st December 2018

10 DATE OF REVISION OF THE TEXT

February 2021