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 Spain 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 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 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

Each carton contains 100 tablets. Each blister strip contains 10 tablets.

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/229/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th September 2024

10 DATE OF REVISION OF THE TEXT

February 2026