BUPROPION- bupropion tablet, extended release
Zydus Lifesciences Limited

BUPROPION HYDROCHLORIDE EXTENDED-RELEASE TABLETS (XL)

Manufactured by:

Cadila Healthcare Ltd.

India.

SPL MEDGUIDE

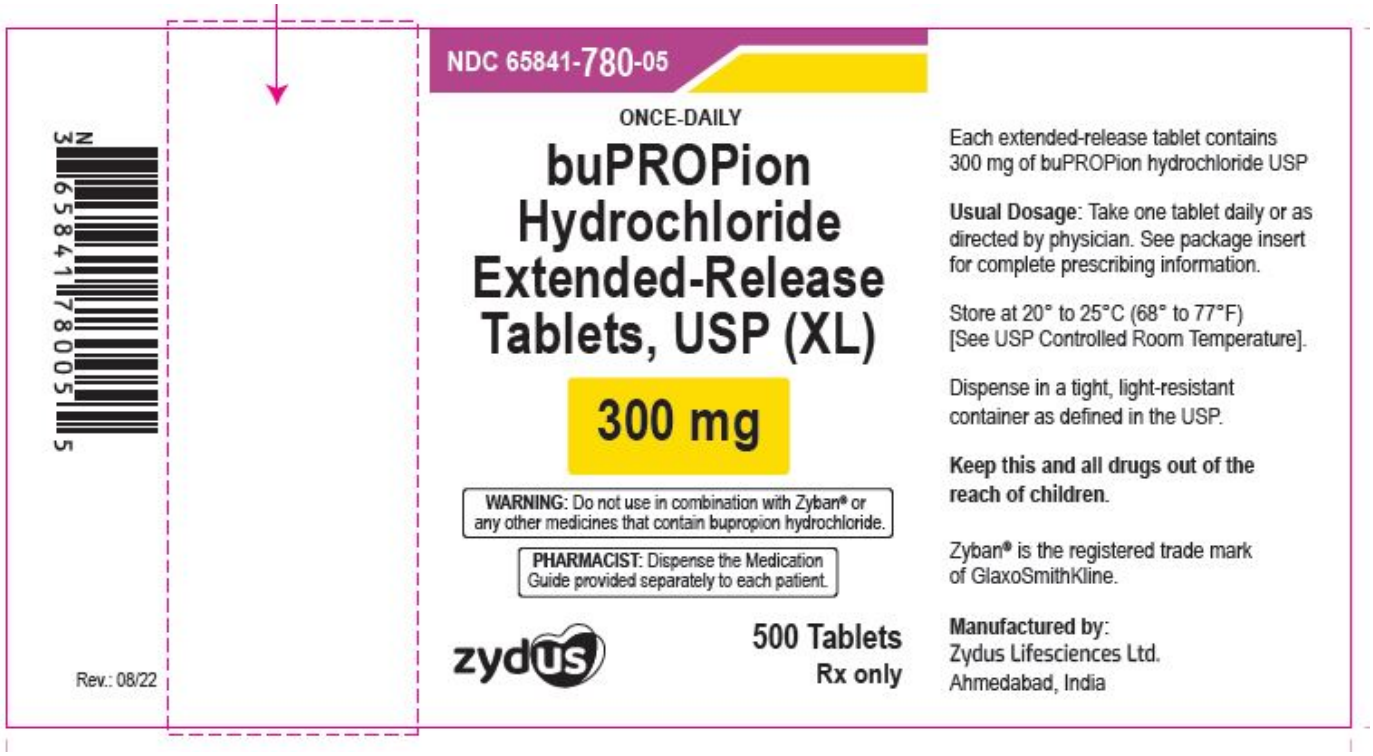
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-780-05

Bupropion Hydrochloride Extended-release Tablets USP (XL), 300 mg

500 Tablets

Rx only

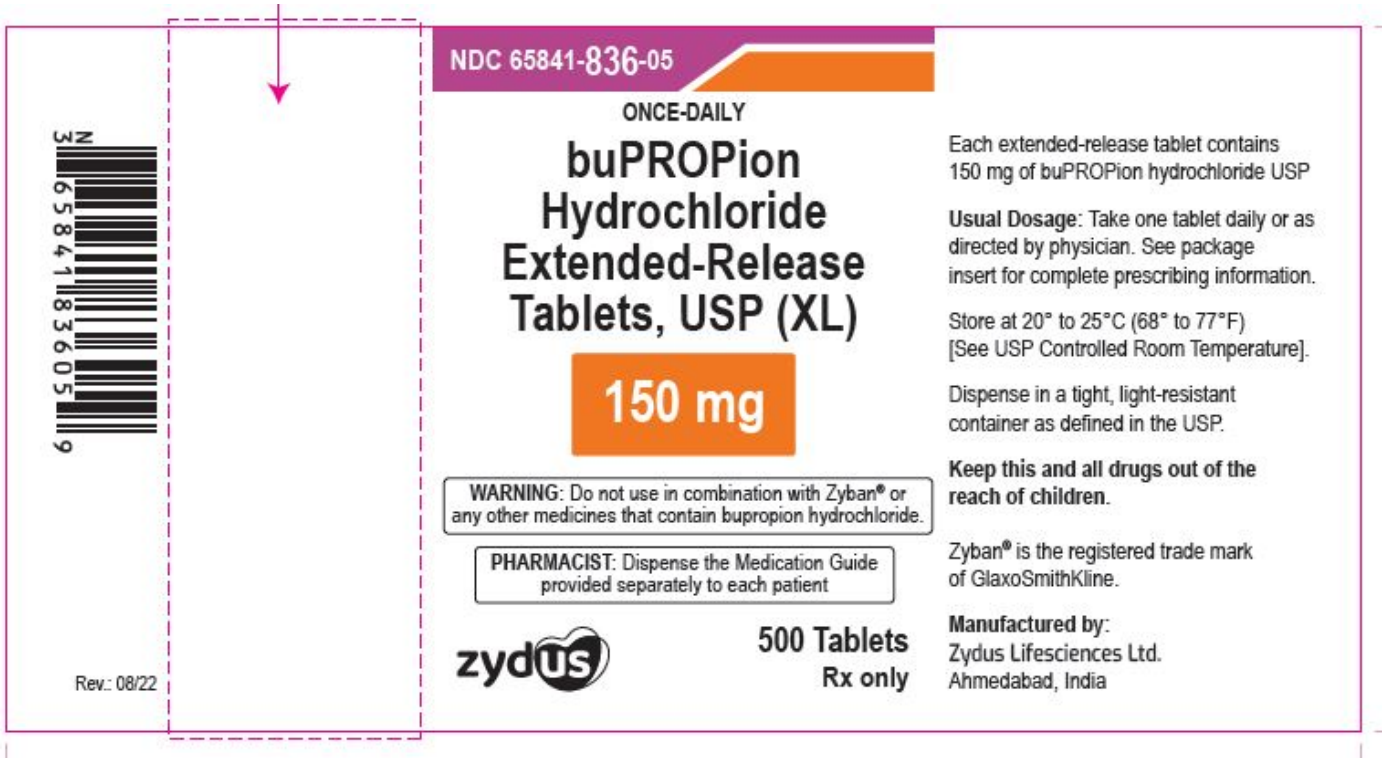


NDC 65841-836-05

Bupropion Hydrochloride Extended-release Tablets USP (XL), 150 mg

500 Tablets

Rx only



BUPROPION

bupropion tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-780
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BUPROPION HYDROCHLORIDE (UNII: ZG7E5POY8O) (BUPROPION - UNII:01ZG3TPX31)	BUPROPION HYDROCHLORIDE	300 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
POVIDONE (UNII: FZ989GH94E)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	

FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	YELLOW (CREAMY WHITE TO PALE YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	354
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-780-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
2	NDC:65841-780-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
3	NDC:65841-780-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
4	NDC:65841-780-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201567	02/15/2014	

BUPROPION

bupropion tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-836
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUPROPION HYDROCHLORIDE (UNII: ZG7E5POY8O) (BUPROPION - UNII:01ZG3TPX31)	BUPROPION HYDROCHLORIDE	150 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
POVIDONE (UNII: FZ989GH94E)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	YELLOW (CREAMY WHITE TO PALE YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	353
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-836-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2018	
2	NDC:65841-836-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2018	
3	NDC:65841-836-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2018	
4	NDC:65841-836-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/02/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201567	08/02/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations

Zydus Lifesciences Limited		918596198	ANALYSIS(65841-780, 65841-836) , MANUFACTURE(65841-780, 65841-836)