

GALANTAMINE- galantamine tablet, film coated
Cadila Healthcare Limited

GALANTAMINE TABLETS

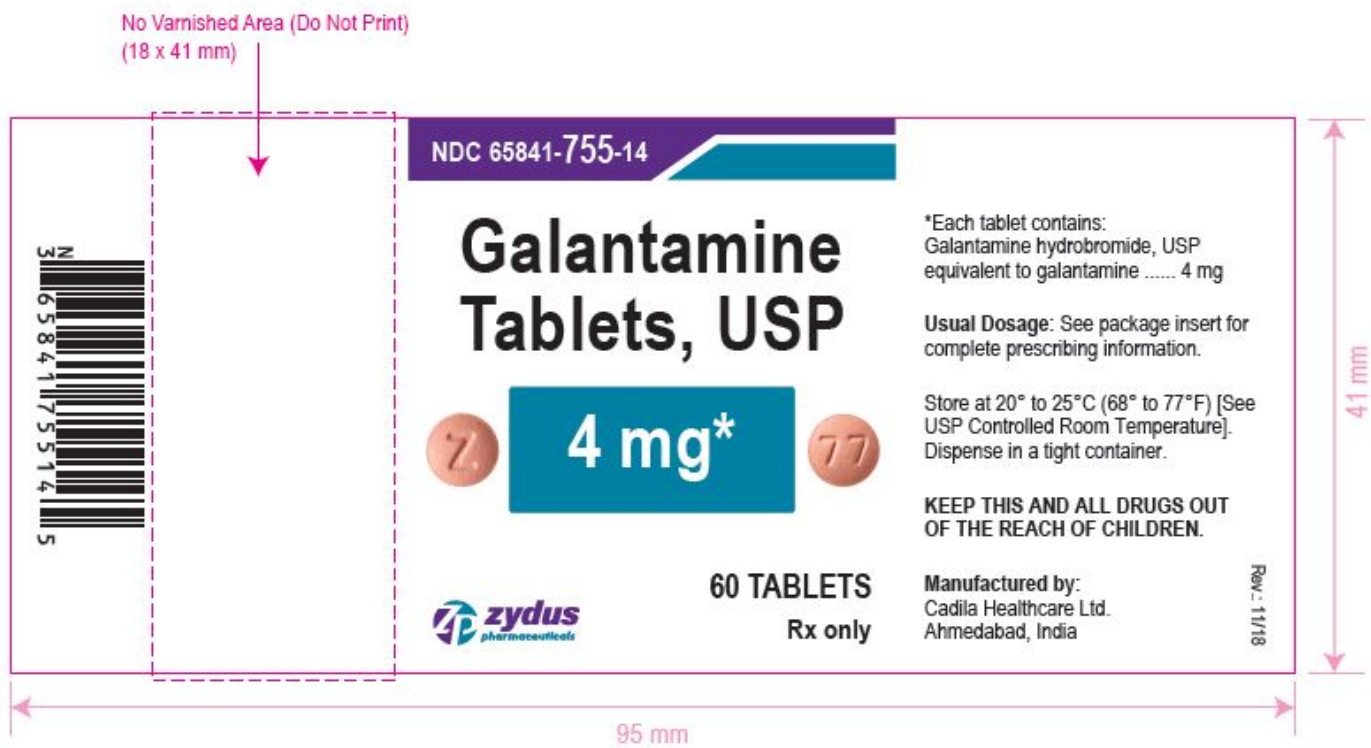
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-755-14 in bottle of 60 tablets

Galantamine Tablets USP, 4 mg

R_x only

60 tablets



NDC 65841-756-14 in bottle of 60 tablets

Galantamine Tablets USP, 8 mg

R_x only

60 tablets

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 65841-756-14

Galantamine Tablets, USP

8 mg*

78

60 TABLETS
Rx only

zydus
pharmaceuticals

*Each tablet contains:
Galantamine hydrobromide, USP
equivalent to galantamine 8 mg

Usual Dosage: See package insert for
complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See
USP Controlled Room Temperature].
Dispense in a tight container.

**KEEP THIS AND ALL DRUGS OUT
OF THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 11/18

95 mm

41 mm

NDC 65841-757-14 in bottle of 60 tablets
Galantamine Tablets USP, 12 mg
Rx only
60 tablets

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 65841-757-14

Galantamine Tablets, USP

12 mg*

79

60 TABLETS
Rx only

zydus
pharmaceuticals

*Each tablet contains:
Galantamine hydrobromide, USP
equivalent to galantamine 12 mg

Usual Dosage: See package insert for
complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See
USP Controlled Room Temperature].
Dispense in a tight container.

**KEEP THIS AND ALL DRUGS OUT
OF THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 11/18

95 mm

41 mm

GALANTAMINE

galantamine tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-755
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GALANTAMINE HYDROBROMIDE (UNII: MJ4PTD2VWV) (GALANTAMINE - UNII:0D3Q044KCA)	GALANTAMINE	4 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CROSPROVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	

Product Characteristics

Color	PINK (LIGHT PINK)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	77;Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-755-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
2	NDC:65841-755-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
3	NDC:65841-755-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
4	NDC:65841-755-77	10 in 1 CARTON	10/10/2011	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078898	10/10/2011	

GALANTAMINE

galantamine tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-756
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GALANTAMINE HYDROBROMIDE (UNII: MJ4PTD2VVW) (GALANTAMINE - UNII:0D3Q044KCA)	GALANTAMINE	8 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	78;Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-756-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
2	NDC:65841-756-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
3	NDC:65841-756-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
4	NDC:65841-756-77	10 in 1 CARTON	10/10/2011	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078898	10/10/2011	

GALANTAMINE

galantamine tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-757
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GALANTAMINE HYDROBROMIDE (UNII: MJ4PTD2VVW) (GALANTAMINE - UNII:0D3Q044KCA)	GALANTAMINE	12 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	WHITE (OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	79;Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-757-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
2	NDC:65841-757-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
3	NDC:65841-757-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2011	
4	NDC:65841-757-77	10 in 1 CARTON	10/10/2011	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078898	10/10/2011	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(65841-755, 65841-756, 65841-757) , MANUFACTURE(65841-755, 65841-756, 65841-757)

Revised: 8/2020

Cadila Healthcare Limited