

**GALANTAMINE - galantamine tablet, film coated**  
**Zydus Lifesciences Limited**

**GALANTAMINE TABLETS**

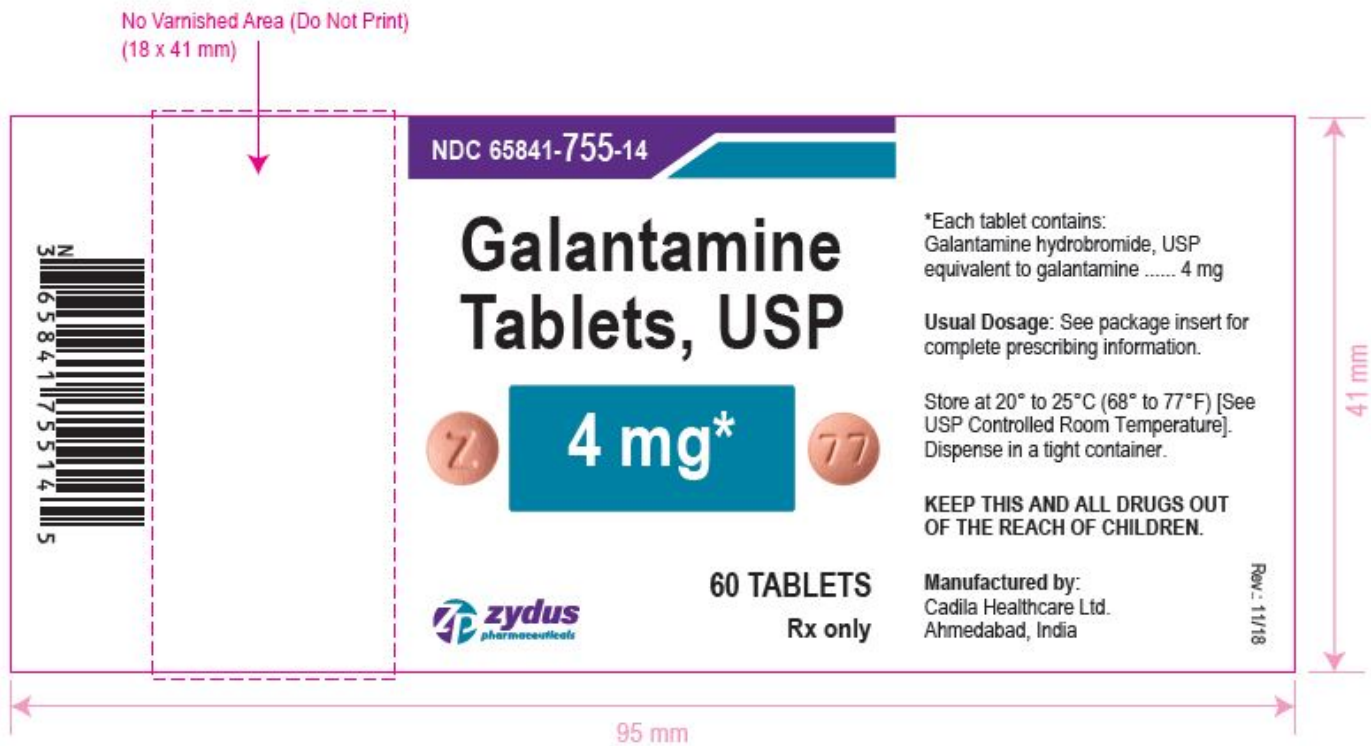
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-755-14 in bottle of 60 tablets

Galantamine Tablets USP, 4 mg

R<sub>x</sub> only

60 tablets



NDC 65841-756-14 in bottle of 60 tablets

Galantamine Tablets USP, 8 mg

R<sub>x</sub> only

60 tablets

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

NDC 65841-756-14

**Galantamine  
Tablets, USP**

8 mg\*

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\*

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

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>CROSPVIDONE (15 MPA.S AT 5%)</b> (UNII: 68401960MK)	

## Product Characteristics

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

## 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
<b>GALANTAMINE HYDROBROMIDE</b> (UNII: MJ4PTD2VWV) (GALANTAMINE - UNII:0D3Q044KCA)	GALANTAMINE	8 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE (15 MPA.S AT 5%)</b> (UNII: 68401960MK)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TITANIUM DIOXIDE</b> (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-	1000 in 1 BOTTLE; Type 0: Not a Combination	10/10/2011	

3	756-10	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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GALANTAMINE HYDROBROMIDE</b> (UNII: MJ4PTD2VWV) (GALANTAMINE - UNII:0D3Q044KCA)	GALANTAMINE	12 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSPVIDONE (15 MPA.S AT 5%)</b> (UNII: 68401960MK)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX43802MRT)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	

### Product Characteristics

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

### 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** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

## Establishment

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

Revised: 10/2022

Zydus Lifesciences Limited