CEVIMELINE HYDROCHLORIDE- cevimeline hydrochloride capsule
Zydus Lifesciences Limited

Cevimeline Hydrochloride Capsules
Rx Only

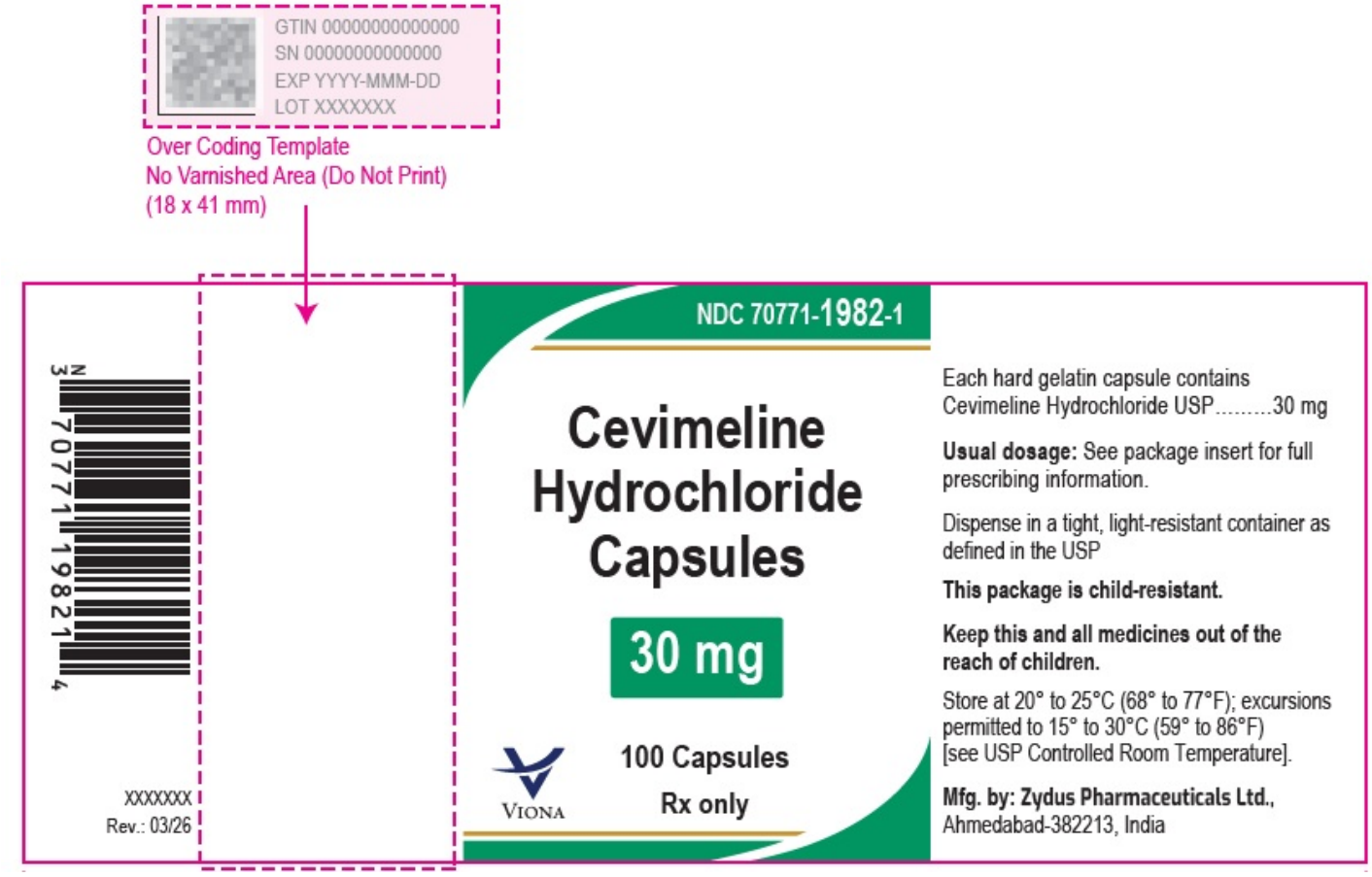
SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Cevimeline Hydrochloride Capsules, 30 mg

NDC 70771-1982-1 in bottles of 100 capsules with child resistant-closure

Rx Only



CEVIMELINE HYDROCHLORIDE

cevimeline hydrochloride capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1982
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CEVIMELINE HYDROCHLORIDE (UNII: P81Q6V85NP) (CEVIMELINE - UNII:K9V0CDQ56E)	CEVIMELINE HYDROCHLORIDE ANHYDROUS	30 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
HYDROXYPROPYL CELLULOSE (20000 WAMW) (UNII: KZQ570MOA5)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

Product Characteristics

Color	WHITE (WHITE OPAQUE)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	1964
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1982-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA220267	04/15/2026	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Pharmaceuticals Limited (650173735)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Pharmaceuticals Limited		650173735	ANALYSIS(70771-1982) , MANUFACTURE(70771-1982)