

SCOPOLAMINE- scopolamine patch, extended release Zydus Lifesciences Limited

SCOPOLAMINE transdermal system

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

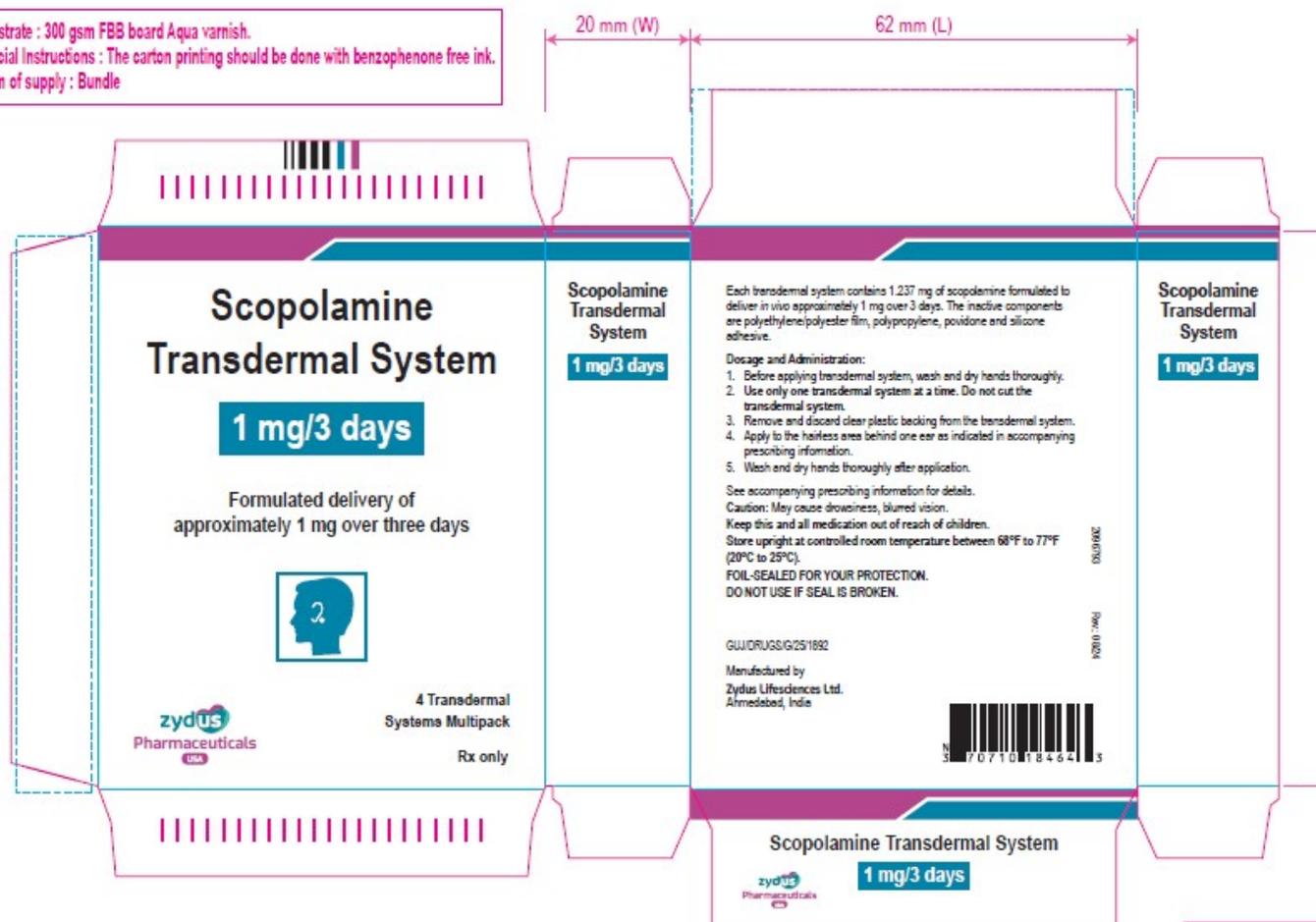
Scopolamine transdermal system, 1 mg/3 days

Carton of 4 transdermal systems

NDC 70771-1787-4

Rx only

Substrate : 300 gsm FBB board Aqua varnish.
Special Instructions : The carton printing should be done with benzophenone free ink.
Form of supply : Bundle



SCOPOLAMINE

scopolamine patch, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1787
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SCOPOLAMINE (UNII: DL48G20X8X) (SCOPOLAMINE - UNII:DL48G20X8X)	SCOPOLAMINE	1 mg in 3 d

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1787-2	10 in 1 CARTON	09/05/2024	
1		1 in 1 POUCH		
1		3 d in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:70771-1787-7	24 in 1 CARTON	09/05/2024	
2		1 in 1 POUCH		
2		3 d in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:70771-1787-4	4 in 1 CARTON	09/05/2024	
3	NDC:70771-1787-1	1 in 1 POUCH		
3		3 d in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217893	09/05/2024	

Labeler - Zydus Lifesciences Limited (918596198)**Establishment**

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650461283	ANALYSIS(70771-1787) , MANUFACTURE(70771-1787)

