LEVOTHYROXINE SODIUM- levothyroxine sodium injection, powder, lyophilized, for solution
Zydus Lifesciences Limited

Levothyroxine Sodium for Injection

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1818-1

Levothyroxine Sodium for Injection

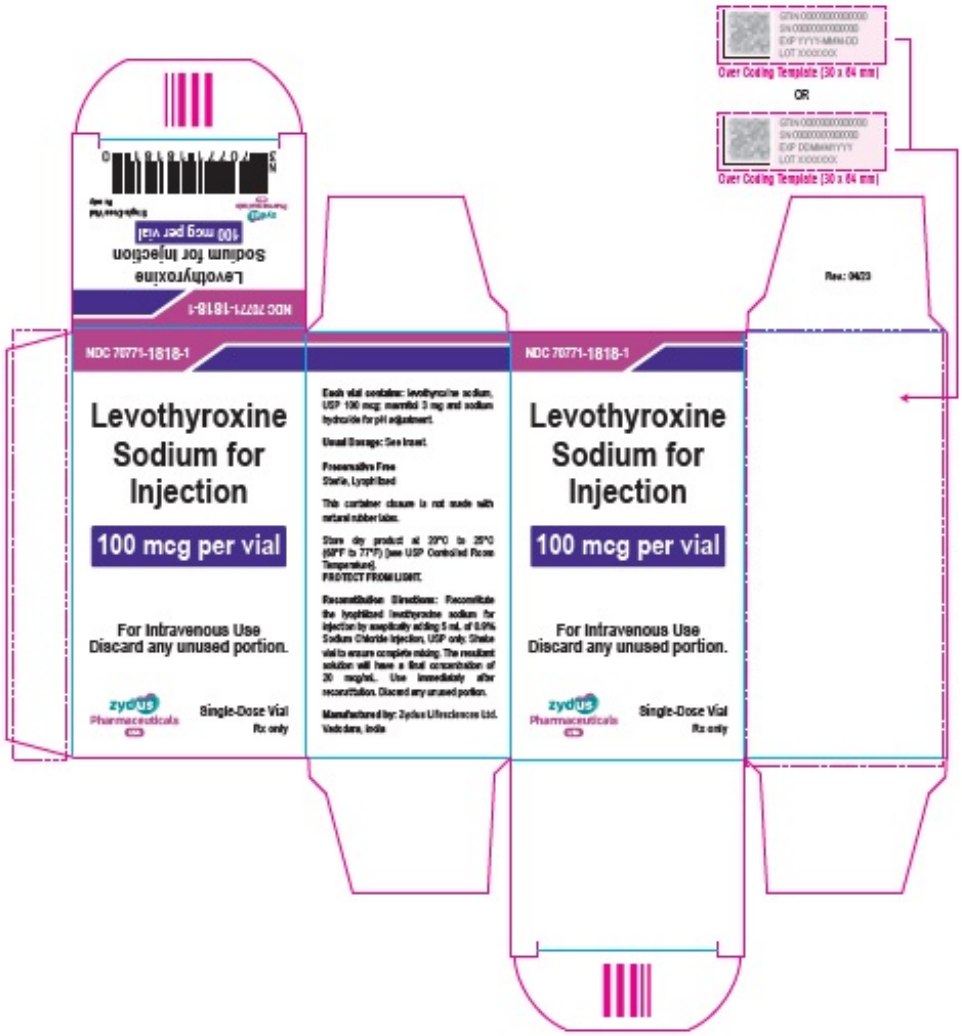
100 mcg per vial

For Intravenous Use

Discard any unused portion

Single-Dose Vial

Rx only



NDC 70771-1819-1

Levothyroxine Sodium for Injection

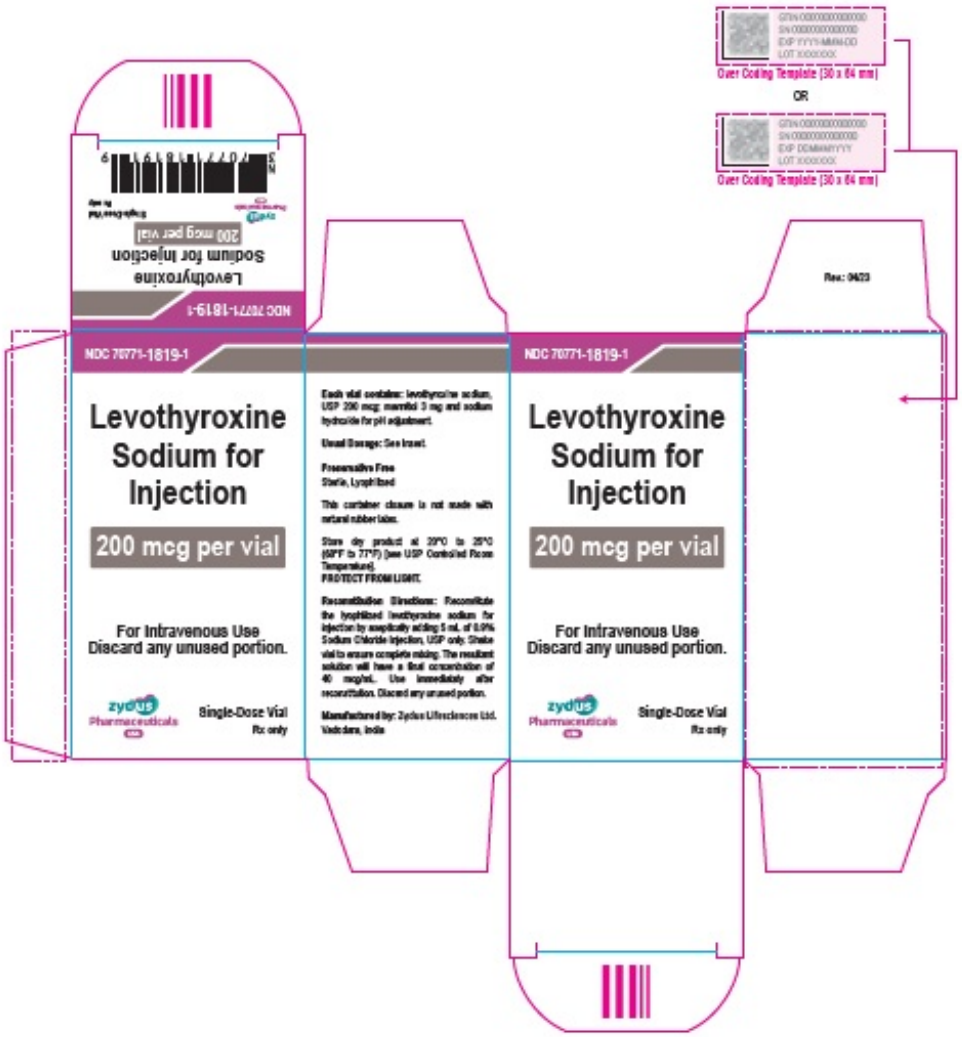
200 mcg per vial

For Intravenous Use

Discard any unused portion

Single-Dose Vial

Rx only



NDC 70771-1820-1

Levothyroxine Sodium for Injection

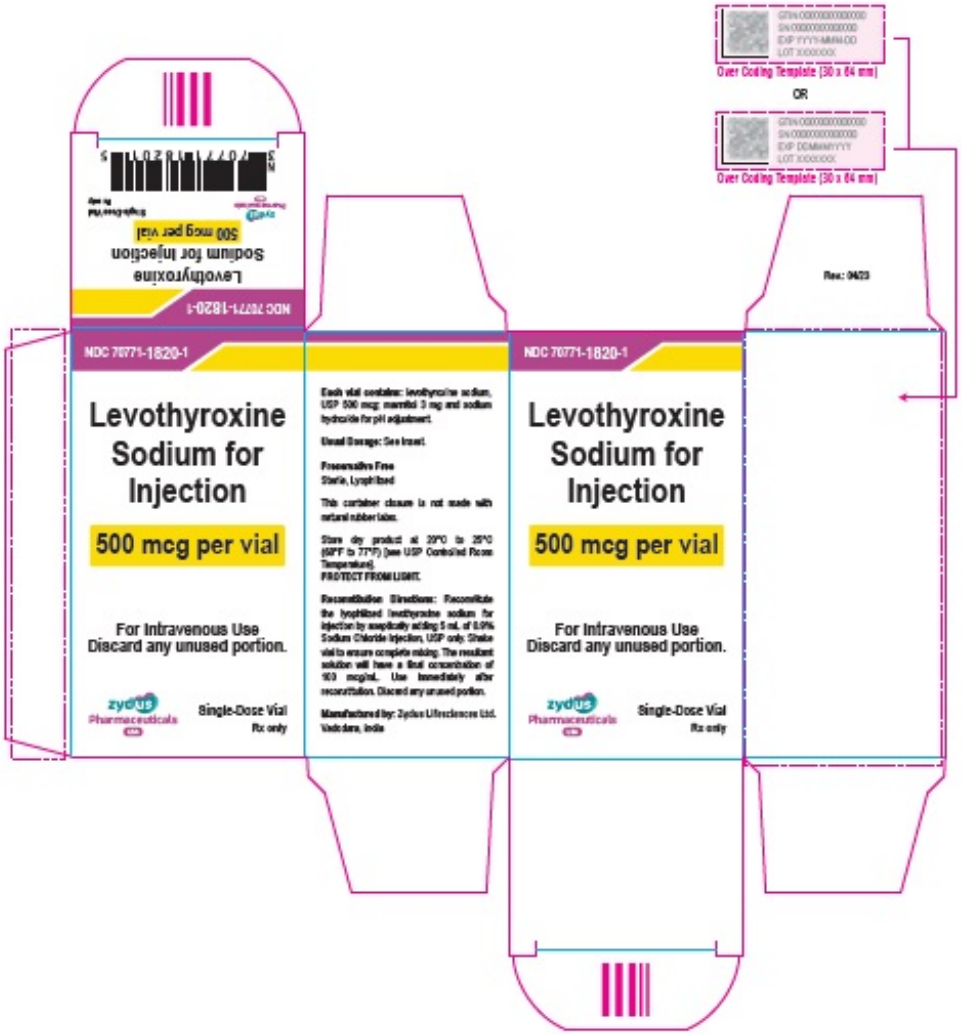
500 mcg per vial

For Intravenous Use

Discard any unused portion

Single-Dose Vial

Rx only



LEVOTHYROXINE SODIUM

levothyroxine sodium injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1818
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM ANHYDROUS (UNII: 054I36CPMN) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	100 ug in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1818-1	1 in 1 CARTON	11/01/2024	
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217066	11/01/2024	

LEVOTHYROXINE SODIUM

levothyroxine sodium injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1819
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOTHYROXINE SODIUM ANHYDROUS (UNII: 054I36CPMN) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	500 ug in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	

Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1819-1	1 in 1 CARTON	11/01/2024	
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217066	11/01/2024	

LEVOTHYROXINE SODIUM

levothyroxine sodium injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1820
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOTHYROXINE SODIUM ANHYDROUS (UNII: 054I36CPMN) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	200 ug in 5 mL

Inactive Ingredients

Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1820-1	1 in 1 CARTON	11/01/2024	
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217066	11/01/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		873671928	MANUFACTURE(70771-1818, 70771-1819, 70771-1820) , ANALYSIS(70771-1818, 70771-1819, 70771-1820)

Revised: 10/2024 Zydus Lifesciences Limited