

HALOPERIDOL DECANOATE- haloperidol decanoate injection

Zydus Lifesciences Limited

Haloperidol Decanoate Injection For Intramuscular Injection Only

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

50 mg/mL Carton (3 vials per carton)

NDC 70771-1851-9

Haloperidol Decanoate

Injection

50 mg/mL*

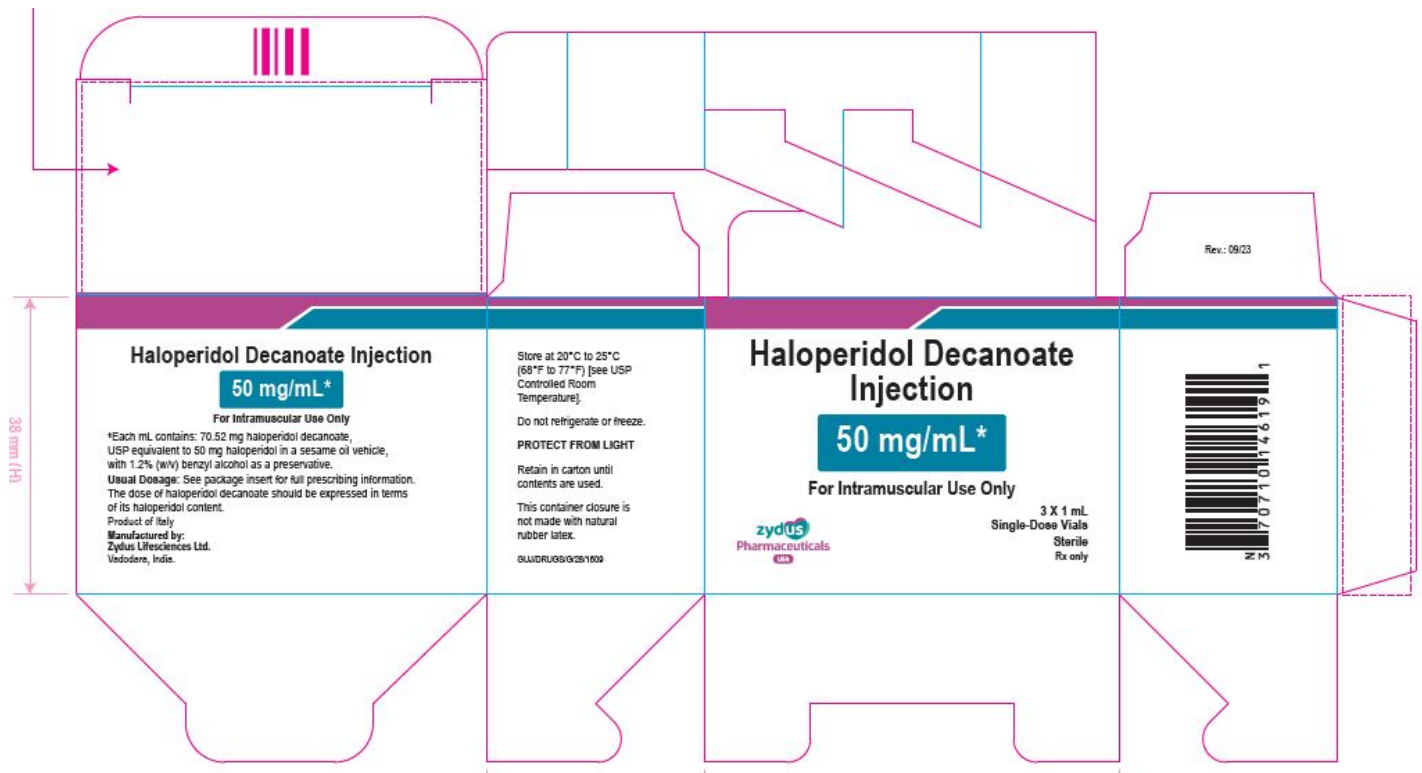
For Intramuscular Use Only

3 X 1 mL

Single-Dose Vials

Sterile

Rx only



250 mg/5 mL (50 mg/mL) Carton (1 vial per carton)

NDC 70771-1852-1

Haloperidol Decanoate Injection

250 mg/5 mL*

(50 mg/mL)

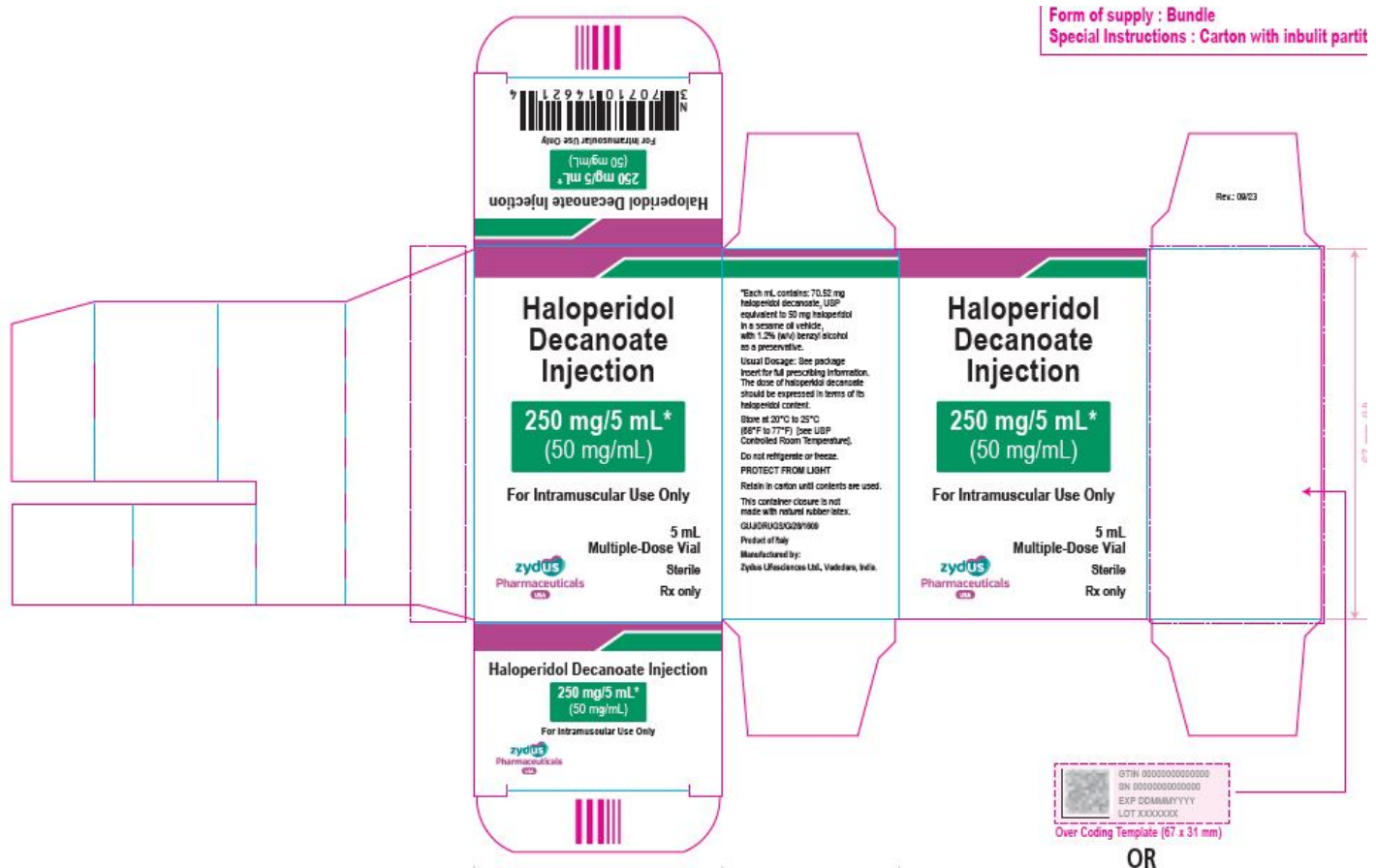
For Intramuscular Use Only

5 mL

Multiple-Dose Vial

Sterile

Rx only



100 mg/mL Carton (1 vial per carton)

NDC 70771-1853-1

Haloperidol Decanoate Injection

100 mg/mL*

For Intramuscular Use Only

1 mL

Single-Dose Vial

Sterile
Rx only

Form of supply : Bundle
Special Instructions : Carton with inbuilt part



500 mg/5 mL (100 mg/mL) Carton (1 vial per carton)

NDC 70771-1854-1

Haloperidol Decanoate Injection

500 mg/5 mL*

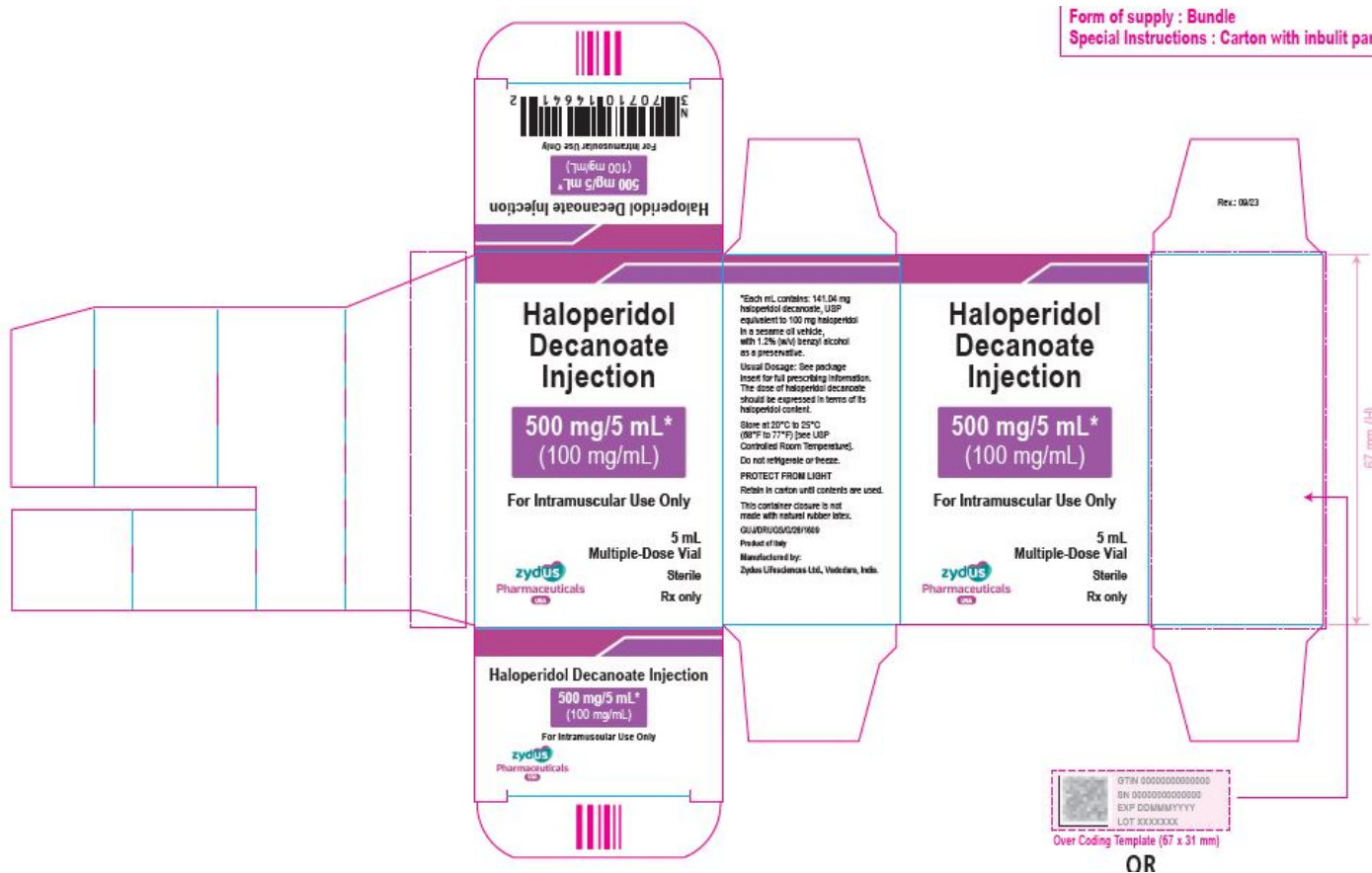
(100 mg/mL)

For Intramuscular Use Only

5 mL Multiple-Dose Vial

Sterile

Rx only



HALOPERIDOL DECANOATE

haloperidol decanoate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1851
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HALOPERIDOL DECANOATE (UNII: AC20PJ4101) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SESAME OIL (UNII: QX10HYY4QV)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:70771-1851-6	10 in 1 CARTON	11/14/2019	
1		1 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:70771-1851-9	3 in 1 CARTON	11/14/2019	
2		1 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	ANDA211180	11/14/2019	

HALOPERIDOL DECANOATE

haloperidol decanoate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1852
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HALOPERIDOL DECANOATE (UNII: AC20PJ4101) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SESAME OIL (UNII: QX10HYY4QV)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1852-1	1 in 1 CARTON	11/14/2019	
1		5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:70771-1852-5	5 in 1 CARTON	11/14/2019	
2		5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211180	11/14/2019	

HALOPERIDOL DECANOATE

haloperidol decanoate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1853
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HALOPERIDOL DECANOATE (UNII: AC20PJ4101) (HALOPERIDOL - UNII:J6292F8L3D)	HALOPERIDOL	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SESAME OIL (UNII: QX10HYY4QV)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1853-1	1 in 1 CARTON	11/14/2019	
1		1 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:70771-1853-5	5 in 1 CARTON	11/14/2019	
2		1 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	ANDA211180	11/14/2019	

HALOPERIDOL DECANOATE

haloperidol decanoate injection

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1854	
Route of Administration	INTRAMUSCULAR			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
HALOPERIDOL DECANOATE (UNII: AC20PJ4101) (HALOPERIDOL - UNII:J6292F8L3D)		HALOPERIDOL	100 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
SESAME OIL (UNII: QX10HYY4QV)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1854-1	1 in 1 CARTON	11/14/2019	
1		5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:70771-1854-5	5 in 1 CARTON	11/14/2019	
2		5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA211180	11/14/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		873671928	MANUFACTURE(70771-1851, 70771-1852, 70771-1853, 70771-1854) , ANALYSIS(70771-1851, 70771-1852, 70771-1853, 70771-1854)