

KYNAMRO- mipomersen sodium injection, solution
Kastle Therapeutics, LLC

KYNAMRO- MIPOMERSEN SODIUM INJECTION, SOLUTION

Principal Display Panel



KYNAMRO				
mipomersen sodium injection, solution				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70688-0502	
Route of Administration	SUBCUTANEOUS			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MIPOMERSEN SODIUM (UNII: 18EAY4870E) (MIPOMERSEN - UNII:9GJ8S4GU0M)		MIPOMERSEN SODIUM	200 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0K00R)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70688-0502-1	1 in 1 CARTON	05/02/2016	
1		1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

2	NDC:70688-0502-2	4 in 1 CARTON	05/02/2016	
2		1 mL in 1 SYRINGE; 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
NDA	NDA203568	05/02/2016	

Labeler - Kastle Therapeutics, LLC (080134022)

Establishment

Name	Address	ID/FEI	Business Operations
Genzyme Corporation		098066215	MANUFACTURE(70688-0502) , ANALYSIS(70688-0502) , PACK(70688-0502) , LABEL(70688-0502)

Establishment

Name	Address	ID/FEI	Business Operations
Genzyme Haverhill		229522842	PACK(70688-0502) , ANALYSIS(70688-0502) , LABEL(70688-0502)

Establishment

Name	Address	ID/FEI	Business Operations
International Laboratory Services, Ltd		777381963	STERILIZE(70688-0502)

Establishment

Name	Address	ID/FEI	Business Operations
Ionis Pharmaceuticals Inc.		011829916	API MANUFACTURE(70688-0502) , ANALYSIS(70688-0502)

Establishment

Name	Address	ID/FEI	Business Operations
PCI Pharma Services		053217022	LABEL(70688-0502) , PACK(70688-0502)

Revised: 1/2017

Kastle Therapeutics, LLC