HALAVEN- eribulin mesylate injection
BSP Pharmaceuticals SpA

HALAVEN®(eribulin mesylate) injection 0.5 mg/mL

Halaven®

(eribulin mesylate) Injection, for intravenous use
1 mg/2 mL (0.5 mg/mL)

PRINCIPAL DISPLAY PANEL - SHIPPER LABEL

Eisai Manufacturing Limited

Allegato DQA-035/XXXX

New Chemical Entity Demand Chain Unit European Knowledge Centre

Mosquito Way-Hatfield, Herts, AL 109SN

United Kingdom

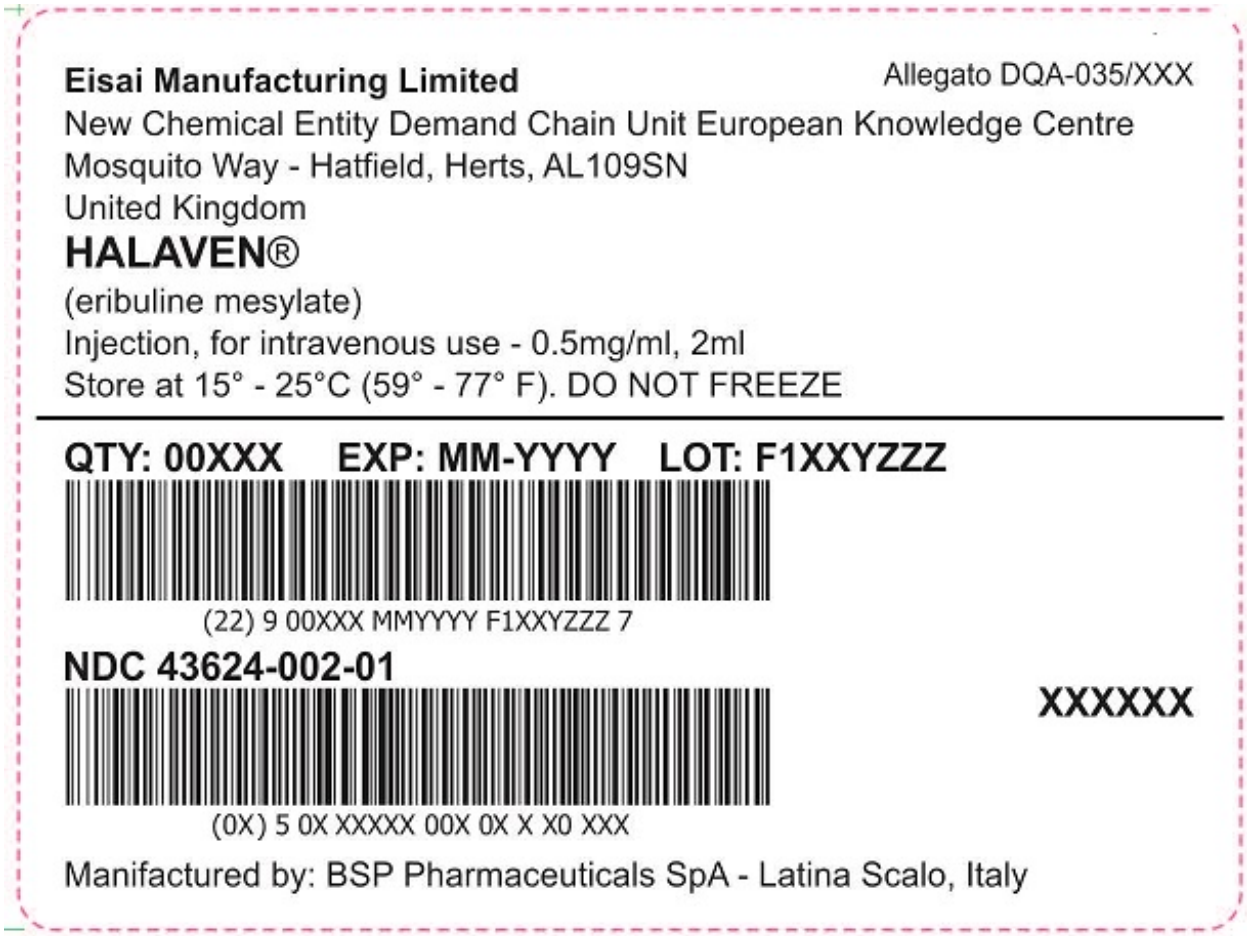
HALAVEN®
(eribulin mesylate) Injection, for intravenous use- 0.5mg/ml, 2 ml
Store at 15° - 25°C (59° - 77°F). DO NOT FREEZE

QTY: 00XXX EXP: MM-YYYY LOT: F1XXYZZZ
(22) 900XXX MMYYYY F1XXYZZZ 7

NDC 43624-002-01

(0X) 50X XXXXX 00X X X0 XXX

Manufactured by : BSP Pharmaceuticals SpA-Latina Scalo, Italy.



HALAVEN

eribulin mesylate injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43624-002
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ERIBULIN MESYLATE (UNII: AV9U0660CW) (ERIBULIN - UNII:LR24G6354G)	ERIBULIN MESYLATE	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white (clear, colorless, sterile solution for intravenous administration)	**Score**	
Shape		**Size**	

Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43624-002-01	100 in 1 BOX, UNIT-DOSE	04/21/2017	
1		3 mL in 1 TRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA201532	04/21/2017	

Labeler - BSP Pharmaceuticals SpA (857007830)

Registrant - BSP Pharmaceuticals SpA (857007830)

Establishment

Name	Address	ID/FEI	Business Operations
BSP Pharmaceuticals SpA		857007830	manufacture(43624-002)

Revised: 11/2023 BSP Pharmaceuticals SpA