

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.

Eisai Manufacturing Limited

Allegato DQA-035/XXX

New Chemical Entity Demand Chain Unit European Knowledge Centre

Mosquito Way - Hatfield, Herts, AL109SN

United Kingdom

HALAVEN®

(eribuline mesylate)

Injection, for intravenous use - 0.5mg/ml, 2ml

Store at 15° - 25°C (59° - 77° F). DO NOT FREEZE

QTY: 00XXX EXP: MM-YYYY LOT: F1XXYZZZ



(22) 9 00XXX MMYYYY F1XXYZZZ 7

NDC 43624-002-01



(0X) 5 0X XXXXX 00X 0X X X0 XXX

XXXXXX

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: 12/2025

BSP Pharmaceuticals SpA