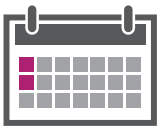
Quick 2- to 5-minute infusion

RECOMMENDED HALAVEN® ADMINISTRATION[1]

	DOSE	INFUSION TIME	SCHEDULE
Recommended dose	**1.4 mg/m²**	**2 to 5 minutes** 	**Days 1 and 8** (21-day cycle) 
In patients with • Mild hepatic impairment[a]	1.1 mg/m²		
• Moderate hepatic impairment[b]	0.7 mg/m²		
• Moderate or severe renal impairment[c]	1.1 mg/m²		

[a]Mild hepatic impairment=Child-Pugh A.
[b]Moderate hepatic impairment=Child-Pugh B.
[c]Creatinine clearance (CLcr) of 15-49 mL/min.

- Patients with severe hepatic impairment (Child-Pugh C) were not studied[1]

Recommended dosing schedule and modifications

Manage ARs with dose delays, reductions, and/or discontinuations[1]*

- Assess for peripheral neuropathy and obtain complete blood cell counts prior to each dose
- Do not administer HALAVEN on Day 1 or Day 8 in patients with ≥Grade 3 neutropenia,† ≥Grade 2 thrombocytopenia,‡ or Grade 3/4 nonhematologic toxicities
- **The Day 8 dose may be delayed for up to 1 week** in patients with toxicities
  - If toxicities resolve or improve to Grade 2 or less by Day 15, administer at a reduced dose and initiate the next cycle no sooner than 2 weeks later
  - If toxicities do not resolve or improve to Grade 2 or less by Day 15, omit the dose
- If a dose has been delayed for toxicities that have recovered to a severity of Grade 2 or less, resume at the recommended reduced dose
- If a dose has been reduced due to toxicities, do not re-escalate

ANC=absolute neutrophil count.
*Toxicities graded in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events version 3.0.[1]
†Greater than or equal to Grade 3 neutropenia=ANC <1,000/mm³.[2]
‡Greater than or equal to Grade 2 thrombocytopenia=platelets <75,000/mm³.[2]

SEE RECOMMENDED DOSE REDUCTIONS BELOW

Indication

Metastatic Breast Cancer

HALAVEN (eribulin mesylate) Injection is indicated for the treatment of patients with metastatic breast cancer (mBC) who have previously received at least 2 chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.

Selected Safety Information

Warnings and Precautions

Neutropenia: Severe neutropenia (ANC <500/mm³) lasting >1 week occurred in 12% of patients with mBC. Febrile neutropenia occurred in 5% of patients with mBC and 2 patients (0.4%) died from complications. Patients with mBC with elevated liver enzymes >3 × ULN and bilirubin >1.5 × ULN experienced a higher incidence of Grade 4 neutropenia and febrile neutropenia than patients with normal levels. Monitor complete blood cell counts prior to each dose, and increase the frequency of monitoring in patients who develop Grade 3 or 4 cytopenias. Delay administration and reduce subsequent doses in patients who experience febrile neutropenia or Grade 4 neutropenia lasting >7 days.

Please see all Selected Safety Information throughout and full Prescribing Information.

Halaven® (eribulin mesylate) Injection | 0.5 mg/mL

RECOMMENDED DOSE REDUCTIONS[1]*

EVENTS REQUIRING PERMANENT DOSE REDUCTION	CURRENT DOSE	RECOMMENDED DOSE REDUCTION
Hematologic toxicities • ANC <500/mm^3 for >7 days or ANC <1,000/mm^3 with fever or infection • Platelets <25,000/mm^3 or platelets <50,000/mm^3 requiring transfusion Grade 3/4 nonhematologic toxicities Omission or delay of Day 8 dose in previous cycle for toxicity	1.4 mg/m^2	1.1 mg/m^2
Any event requiring permanent dose reduction while receiving 1.1 mg/m^2	1.1 mg/m^2	0.7 mg/m^2
Any event requiring permanent dose reduction while receiving 0.7 mg/m^2	0.7 mg/m^2	Discontinue HALAVEN®

ANC=absolute neutrophil count.
*Toxicities graded in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events version 3.0.[1]

Selected Safety Information

Warnings and Precautions (cont'd)

Peripheral Neuropathy: Grade 3 peripheral neuropathy occurred in 8% of patients with mBC (Grade 4=0.4%) and 22% developed a new or worsening neuropathy that had not recovered within a median follow-up duration of 269 days (range 25-662 days). Neuropathy lasting >1 year occurred in 5% of patients with mBC. Patients should be monitored for signs of peripheral motor and sensory neuropathy. Withhold HALAVEN in patients who experience Grade 3 or 4 peripheral neuropathy until resolution to Grade 2 or less.

Embryo-Fetal Toxicity: HALAVEN can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with HALAVEN and for at least 2 weeks following the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with HALAVEN and for 3.5 months following the final dose.

QT Prolongation: Monitor for prolonged QT intervals in patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, and electrolyte abnormalities. Correct hypokalemia or hypomagnesemia prior to initiating HALAVEN and monitor these electrolytes periodically during therapy. Avoid in patients with congenital long QT syndrome.

Adverse Reactions

In patients with mBC receiving HALAVEN, the most common adverse reactions (≥25%) were neutropenia (82%), anemia (58%), asthenia/fatigue (54%), alopecia (45%), peripheral neuropathy (35%), nausea (35%), and constipation (25%). Febrile neutropenia (4%) and neutropenia (2%) were the most common serious adverse reactions. The most common adverse reaction resulting in discontinuation was peripheral neuropathy (5%).

Use in Specific Populations

Lactation: Because of the potential for serious adverse reactions in breastfed infants from eribulin mesylate, advise women not to breastfeed during treatment with HALAVEN and for 2 weeks after the final dose.

Hepatic and Renal Impairment: A reduction in starting dose is recommended for patients with mild or moderate hepatic impairment and/or moderate or severe renal impairment.

FOR ADDITIONAL RESOURCES, VISIT THE HALAVEN NURSE HUB AT
WWW.HALAVEN.COM/HCP/METASTATIC-BREAST-CANCER/NURSE-HUB

References: 1. HALAVEN [package insert]. Woodcliff Lake, NJ: Eisai Inc. **2.** National Cancer Institute. Cancer Therapy Evaluation Program, Common Terminology Criteria for Adverse Events v3.0. NIH Publication #03-5410. http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf. March 31, 2003. Published August 9, 2006. Accessed June 26, 2018.

Please see all Selected Safety Information throughout and full Prescribing Information.

Price disclosure information for prescribers available at us.eisai.com/RequiredPriceDisclosures.

Halaven® (eribulin mesylate) Injection | 0.5 mg/mL