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

MOMENTS MATTER

HALAVEN® showed a significant overall survival benefit in patients with third-line metastatic breast cancer that included all receptor subtypes[1-4]

HALAVEN improved median overall survival in metastatic breast cancer vs Treatment of Physician's Choice (13.2 months vs 10.6 months) when following 2 prior chemotherapies for metastatic breast cancer.[4]

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/mm^3) 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 HALAVEN full Prescribing Information.

A study design that reflected real-life, single-agent treatment choices

EMBRACE: A PHASE III, RANDOMIZED, OPEN-LABEL, MULTICENTER, MULTINATIONAL TRIAL[1,5,6]

PATIENTS WITH METASTATIC BREAST CANCER (N=762)

- ≥2 chemotherapeutic regimens for metastatic disease
- Prior anthracycline- and taxane-based chemotherapy
- Progression within 6 months of last chemotherapeutic regimen

RANDOMIZATION (2:1)[a]

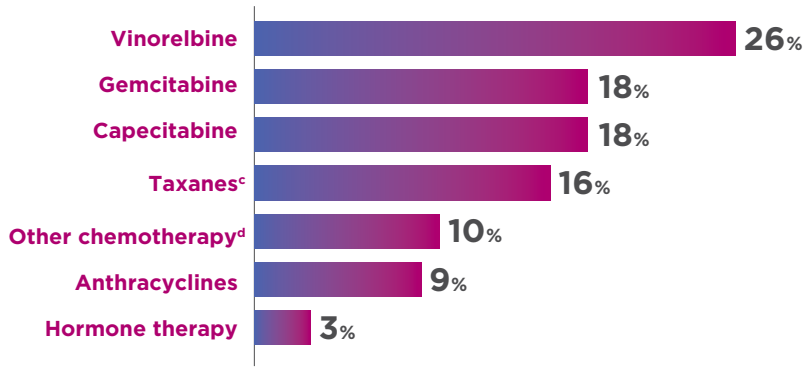
HALAVEN®
(n=508)
1.4 mg/m^2 IV for 2 to 5 minutes Days 1 and 8 (21-day cycle)

TPC
(Control arm, n=254)[b]
Any single-agent therapy, selected prior to randomization

PRIMARY ENDPOINT: OS

EMBRACE=Eisai Metastatic Breast Cancer Study Assessing Physician's Choice versus E7389 (Eribulin); IV=intravenous; TPC=Treatment of Physician's Choice; OS=overall survival; HER2/*neu*=human epidermal growth factor receptor 2.
[a]Randomization was stratified by geographic region, HER2/*neu* status, and prior capecitabine exposure.[4]
[b]Therapies included in the TPC arm were determined prior to randomization to eliminate bias and had to be approved for the treatment of cancer, administered according to local practice, and available at time of study.[1]

THERAPIES IN THE TPC ARM[4]



[c]Included paclitaxel, docetaxel, nab-paclitaxel, and ixabepilone.[1]
[d]Included cisplatin, carboplatin, cyclophosphamide, etoposide, mitomycin, fluorouracil, and methotrexate.[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.

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

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

Studied in patients regardless of visceral or nonvisceral disease

BASELINE PATIENT CHARACTERISTICS[7]

SELECTED PATIENT FACTORS		HALAVEN (n=508)	TPC (n=254)
Median age (range)		55 years (28 to 85)	56 years (27 to 81)
ECOG PS	0	43%	41%
	1	48%	50%
	2	8%	9%
HER2/neu status	Positive	18%	17%
	Negative	81%	83%
	Unknown	1%	0%
ER status	Positive	70%	70%
	Negative	30%	30%
	Unknown	<1%	0%
PR status	Positive	56%	55%
	Negative	44%	45%
	Unknown	<1%	0%
Triple negative	HER2/*neu*-, ER-, PR-	18%	21%
Sites of involvement	Liver	58%	63%
	Lung	39%	37%
	Bone	60%	62%
Metastatic sites	2	34%	32%
	3	29%	30%
	4	14%	15%
Number of prior mBC chemotherapy regimens	2	43%	36%
	3	32%	33%
	4	18%	22%

Metastases included visceral disease

ECOG PS=Eastern Cooperative Oncology Group performance status; ER=estrogen receptor; PR=progesterone receptor.

- Evaluated in patients with pre-existing peripheral neuropathy: at baseline, 17% of enrolled patients had Grade 1 peripheral neuropathy and 3% had Grade 2[4]

Baseline characteristics included the presence of visceral disease[7]

IN THE HALAVEN ARM OF THE EMBRACE TRIAL:

81.3% OF PATIENTS HAD **VISCERAL DISEASE**

Selected Safety Information

Warnings and Precautions (cont'd)

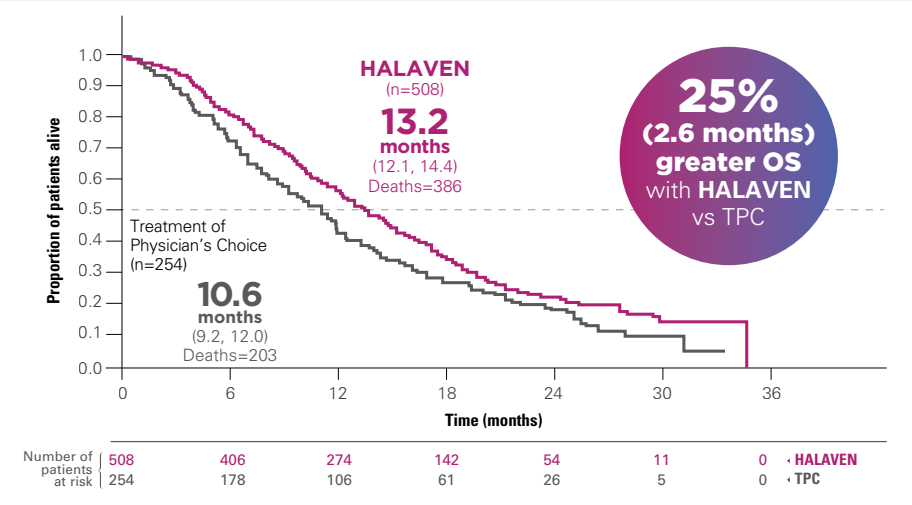
Embryo-Fetal Toxicity: HALAVEN can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with HALAVEN and for at least 2 weeks following the final dose. Advise males with female partners of reproductive potential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

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

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

HALAVEN® significantly extended life in third-line mBC[1-3]

UPDATED OS ANALYSIS (UNPLANNED): MEDIAN OS, MONTHS (95% CI)[1,4,a]



Results from an updated, unplanned survival analysis of the Phase III, randomized (2:1), open-label, multicenter, multinational EMBRACE trial of HALAVEN versus TPC (control arm) in patients with mBC (N=762), conducted when 77% of events (deaths) had been observed.[1,4]

mBC=metastatic breast cancer; OS=overall survival; CI=confidence interval; TPC=Treatment of Physician's Choice; EMBRACE=Eisai Metastatic Breast Cancer Study Assessing Physician's Choice versus E7389 (Eribulin).

[a]Conducted in the intent-to-treat (ITT) population.

- **Results of the updated analysis were consistent with the primary analysis,** which was conducted when ~50% of events (deaths) had been observed. HALAVEN demonstrated a median OS of 13.1 months (95% CI: 11.8, 14.3) vs 10.6 months with the TPC arm (95% CI: 9.3, 12.5), hazard ratio (HR)=0.81 (95% CI: 0.66, 0.99) (*P*=0.041)[1,4]

PATIENTS RECEIVING HALAVEN LIVED A MEDIAN OF **13.2 MONTHS**, COMPARED TO **10.6 MONTHS** FOR PATIENTS RECEIVING TPC[4]

Selected Safety Information

Warnings and Precautions (cont'd)

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.

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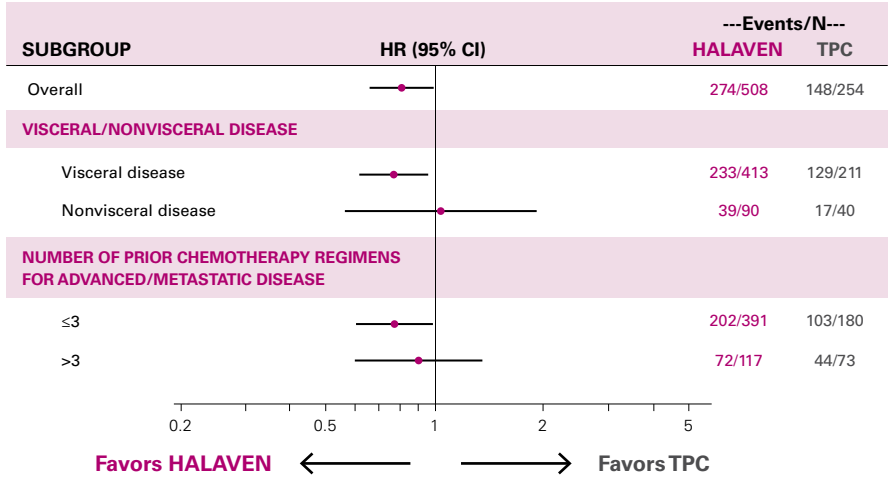
Halaven® (eribulin mesylate) Injection | 0.5 mg/mL

Exploratory analysis: OS by patient subgroups

OS FOREST PLOT OF HAZARD RATIOS IN THE ITT POPULATION[7]



Limitations[1,7]

- Exploratory subgroup analyses were not prespecified, adjusted for multiplicity, or powered to show statistical significance
- The wide and overlapping CIs and small numbers of subjects in certain subgroups mean that no conclusions can be drawn

Selected Safety Information

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%).

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Safety profile demonstrated in the Phase III EMBRACE trial

ADVERSE REACTIONS[4,a]

		HALAVEN® (n=503)		TPC (n=247)	
INCIDENCE ≥10% BY GRADE		**All**	**≥3**	**All**	**≥3**
Blood and lymphatic system disorders[b]	Neutropenia	82%	57%	53%	23%
	Anemia	58%	2%	55%	4%
Nervous system disorders	Peripheral neuropathy[c]	35%	8%	16%	2%
	Headache	19%	<1%	12%	<1%
General disorders	Asthenia/fatigue	54%	10%	40%	11%
	Pyrexia	21%	<1%	13%	<1%
	Mucosal inflammation	9%	1%	10%	2%
Gastrointestinal disorders	Nausea	35%	1%	28%	3%
	Constipation	25%	1%	21%	1%
	Vomiting	18%	1%	18%	1%
	Diarrhea	18%	0%	18%	0%
Musculoskeletal and connective tissue disorders	Arthralgia/myalgia	22%	<1%	12%	1%
	Back pain	16%	1%	7%	2%
	Bone pain	12%	2%	9%	2%
	Pain in extremity	11%	1%	10%	1%
Metabolism and nutrition disorders	Decreased weight	21%	1%	14%	<1%
	Anorexia	20%	1%	13%	1%
Respiratory, thoracic, and mediastinal disorders	Dyspnea	16%	4%	13%	4%
	Cough	14%	0%	9%	0%
Skin and subcutaneous tissue disorders	Alopecia	45%	NA[d]	10%	NA[d]
Infections	Urinary tract infection	10%	1%	5%	0%

[a]Adverse reactions were graded per the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.0.[4]

[b]Based upon laboratory data.[4]

[c]Includes peripheral neuropathy, peripheral sensorimotor neuropathy, peripheral motor neuropathy (in the HALAVEN arm: all Grades=4%, Grade 3=2%), polyneuropathy, peripheral sensory neuropathy, and paresthesia.[4]

[d]Not applicable; grading system does not specify greater than Grade 2 for alopecia. Rate of alopecia in the HALAVEN arm: Grade 1=26%, Grade 2=17%. Rate of alopecia in the TPC arm: Grade 1=5%, Grade 2=5%.[4,7]

OF THE PATIENTS RECEIVING HALAVEN:

87%

DID **NOT** HAVE **ADVERSE EVENTS LEADING TO DISCONTINUATION**[1]

- 13% of patients receiving HALAVEN had adverse events leading to discontinuation vs 15% in the TPC arm

- Median duration of exposure was 118 days in the HALAVEN arm and 63 days in the TPC arm[4]

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

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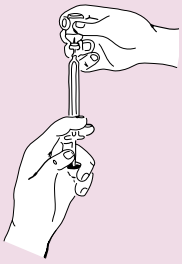
Straightforward preparation

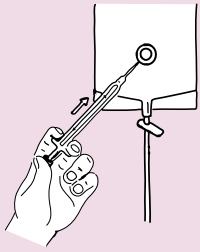
ADMINISTER UNDILUTED OR DILUTED BY IV INFUSION[4]

Each single-use vial contains 1 mg of HALAVEN in 2 mL of solution (0.5 mg/mL)



To administer undiluted, aseptically withdraw required amount of HALAVEN from vial

OR



To dilute, aseptically withdraw required amount of HALAVEN from vial and dilute in 100 mL of 0.9% Sodium Chloride Injection, USP

- **Do not dilute in or administer through an intravenous line containing solutions with dextrose.** Do not administer in the same intravenous line with other medicinal products

IV=intravenous.

Storage[4]

- Store HALAVEN vials at 77°F (25°C); excursions permitted to 59°F-86°F (15°C-30°C)
- Do not freeze or refrigerate
- Store vials in original cartons
- Undiluted HALAVEN may be stored in the syringe for up to 4 hours at room temperature or for up to 24 hours under refrigeration (40°F or 4°C)
- Diluted HALAVEN may be stored for up to 4 hours at room temperature or for up to 24 hours under refrigeration
- Discard unused portions of the vial

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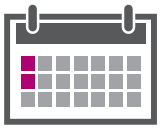
A quick 2- to 5-minute infusion

RECOMMENDED HALAVEN® ADMINISTRATION[4]

	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[4]

- ✓ NO KNOWN DRUG-DRUG INTERACTIONS[4]
- ✓ NO PREMEDICATION REQUIRED[7]
- ✓ NO PREMIXING REQUIRED[4]
- ✓ NO CREMOPHOR® OR POLYSORBATE 80 IN THE HALAVEN FORMULATION[7]

Cremophor® EL Castor Oil is a registered trademark of BASF Corporation or BASF SE.

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

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

Recommended dosing schedule and modifications

Manage ARs with dose delays, reductions, and/or discontinuations[4]*

- 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

RECOMMENDED DOSE REDUCTIONS[4]*

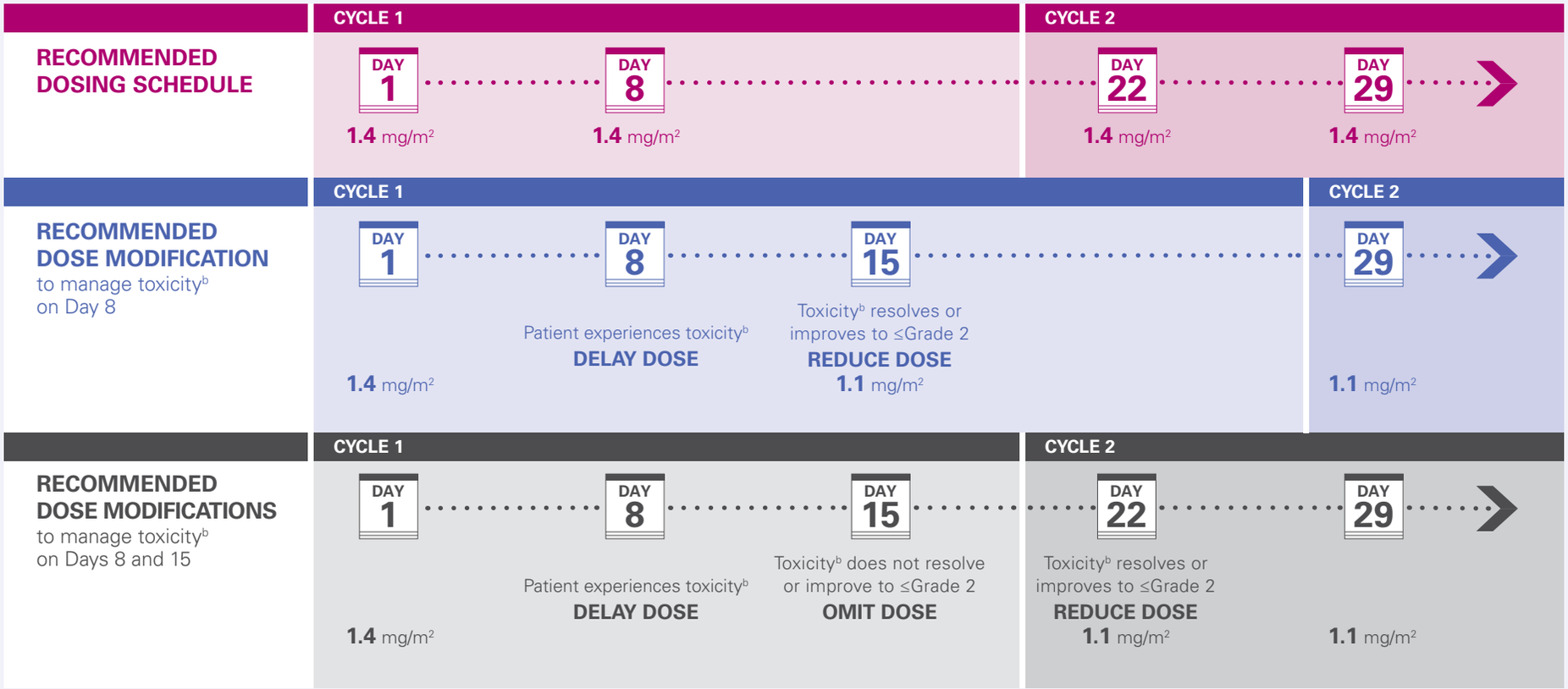
EVENTS REQUIRING PERMANENT DOSE REDUCTION	CURRENT DOSE	RECOMMENDED DOSE REDUCTION
Hematologic toxicities • ANC <500/mm^3 for >7 days or ANC <1,000/mm^3 with fever or infection • Platelets <25,000/mm^3 or platelets <50,000/mm^3 requiring transfusion Grade 3/4 nonhematologic toxicities Omission or delay 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

AR=adverse reaction; ANC=absolute neutrophil count.
*Toxicities graded in accordance with NCI CTCAE version 3.0.[4]
†Greater than or equal to Grade 3 neutropenia=ANC <1,000/mm^3.[8]
‡Greater than or equal to Grade 2 thrombocytopenia=platelets <75,000/mm^3.[8]

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

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

RECOMMENDED DOSING SCHEDULE AND MODIFICATIONS[4,a]



[a]Toxicities graded in accordance with NCI CTCAE version 3.0.[4]
[b]Toxicities include ≥Grade 3 neutropenia (ANC <1,000/mm³), ≥Grade 2 thrombocytopenia (platelets <75,000/mm³), or Grade 3/4 nonhematologic toxicities.[4,8]

- For any event requiring permanent dose reduction while receiving 1.1 mg/m², reduce to 0.7 mg/m² of HALAVEN®[4]
- For any event requiring permanent dose reduction while receiving 0.7 mg/m², discontinue HALAVEN[4]

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

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Monitor patients prior to and throughout therapy

PATIENT MONITORING[4]

Peripheral neuropathy	• Monitor closely throughout treatment for signs of peripheral motor and sensory neuropathy
Neutropenia	• Monitor complete blood counts prior to each dose; increase the frequency of monitoring in patients who develop Grade 3 or 4 cytopenias
QT prolongation	• In patients with cardiac disease,[a] ECG monitoring is recommended — In patients with electrolyte abnormalities, correct hypokalemia or hypomagnesemia prior to initiating HALAVEN and monitor these electrolytes periodically

ECG=electrocardiogram.

[a]Consisting of patients with congestive heart failure; bradyarrhythmias; electrolyte abnormalities; and those receiving drugs known to prolong the QT interval, including Class Ia and III antiarrhythmics. Avoid HALAVEN in patients with congenital long QT syndrome.

ACCESS MEDICAL INFORMATION THROUGH EISAI MEDICAL INFORMATION AT 1.888.274.2378
(MONDAY-FRIDAY, 8:30 AM TO 5 PM, ET)

References: 1. Cortes J, O'Shaughnessy J, Loesch D, et al; EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389) investigators. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomised study. *Lancet.* 2011;377(9769):914-923. **2.** Saad ED, Katz A, Buyse M. Overall survival and post-progression survival in advanced breast cancer: a review of recent randomized clinical trials. *J Clin Oncol.* 2010;28(11):1958-1962. **3.** Sparano JA, Vrdoljak E, Rixe O, et al. Randomized phase III trial of ixabepilone plus capecitabine versus capecitabine in patients with metastatic breast cancer previously treated with an anthracycline and a taxane. *J Clin Oncol.* 2010;28(20):3256-3263. **4.** HALAVEN [package insert]. Nutley, NJ: Eisai Inc. **5.** Testori A, Richards J, Whitman E, et al. Phase III comparison of vitespen, an autologous tumor-derived heat shock protein gp96 peptide complex vaccine, with physician's choice of treatment for stage IV melanoma: the C-100-21 study group. *J Clin Oncol.* 2008;26(6):955-962. **6.** Cree IA, Kurbacher CM, Lamont A, Hindley AC, Love S; TCA Ovarian Cancer Trial Group. A prospective randomized controlled trial of tumour chemosensitivity assay directed chemotherapy versus physician's choice in patients with recurrent platinum-resistant ovarian cancer. *Anticancer Drugs.* 2007;18(9):1093-1101. **7.** Data on file, Eisai Inc. **8.** National Cancer Institute. Cancer Therapy Evaluation Program, Common Terminology Criteria for Adverse Events v3.0. NIH Publication #03-5410. http://www.eortc.be/services/doc/ctc/ctcaev3.pdf. Published March 31, 2003. Updated August 9, 2006. Accessed April 17, 2019.

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Because patient accessibility matters

HALAVEN® $0 Co-Pay Program

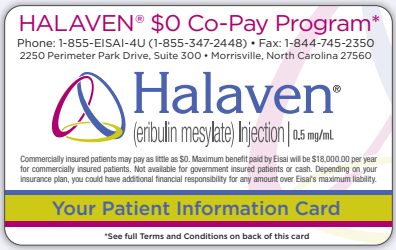
Simplified paperwork—no income requirements

The HALAVEN $0 Co-Pay Program assists eligible, commercially insured patients with the out-of-pocket costs of HALAVEN (up to $18,000 per year). Restrictions apply. Visit **www.eisaireimbursement.com/hcp/halaven** to see the full terms and conditions and eligibility requirements, to learn more about the program, and to download an enrollment form. Eligible, commercially insured patients may pay as little as $0 per month, with an annual limit of $18,000. See **www.eisaireimbursement.com/hcp/halaven** for complete eligibility requirements and terms and conditions.

To qualify,* patients must

- Be covered by commercial insurance
- Not be enrolled in state or federal health care programs, including Medicare, Medicaid, Medigap, VA, DoD, or TRICARE

*Other eligibility requirements may apply.



Reimbursement†

- **Insurance verification and coverage options** with an approximate 24- to 48-hour turnaround for all queries
- **Information about the prior authorization process**
- **Information about the claims and denials appeals process**
- **Patient assistance** and free product to eligible patients

LEARN MORE ABOUT THE HALAVEN $0 CO-PAY PROGRAM BY CALLING **1.855.EISAI.4U** (1.855.347.2448) MONDAY-FRIDAY, 8 AM TO 5 PM, ET

LEARN MORE ABOUT THE EISAI ASSISTANCE PROGRAM FOR HALAVEN BY CALLING **1.866.61.EISAI** (1.866.613.4724) MONDAY-FRIDAY, 8 AM TO 8 PM, ET

OR BY VISITING **WWW.EISAIREIMBURSEMENT.COM/HCP/HALAVEN**

†**Eisai cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. For additional information, customers should consult with their payers for all relevant coding, reimbursement, and coverage requirements. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient medical record.**

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

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HALAVEN® offers a meaningful survival benefit and an established safety profile[4]

HALAVEN may be appropriate for patients **who are ready for chemotherapy in third-line mBC** and who have received 2 prior chemotherapies for mBC. Their previous treatment should have included an anthracycline and a taxane in the adjuvant or metastatic setting.[4]

PATIENTS IN THE HALAVEN ARM OF THE EMBRACE TRIAL:

DEMONSTRATED

25% (2.6 months) greater OS vs TPC

13.2 MONTHS (95% CI: 12.1, 14.4; DEATHS=386) **MEDIAN OS VS 10.6 MONTHS** WITH THE TPC ARM* (95% CI: 9.2, 12.0; DEATHS=203)[4]

81.3%

HAD **VISCERAL DISEASE**[7†]

A GROWING BODY OF REAL-WORLD EXPERIENCE

Over **230,000** patients have been prescribed worldwide[7‡]

IN **MORE THAN 70 COUNTRIES**, WITH **OVER 65,000 PATIENTS** IN THE US[7§]

mBC=metastatic breast cancer; EMBRACE=Eisai Metastatic Breast Cancer Study Assessing Physician's Choice versus E7389 (Eribulin); OS=overall survival; TPC=Treatment of Physician's Choice; CI=confidence interval.

*Therapies in the TPC arm consisted of 97% chemotherapy (26% vinorelbine, 18% gemcitabine, 18% capecitabine, 16% taxanes [including paclitaxel, docetaxel, nab-paclitaxel, and ixabepilone], 9% anthracyclines, and 10% other chemotherapy) and 3% hormone therapy[1,4]

†Visceral disease includes liver and lung metastases.

‡Indications may differ in other countries.

§Patient treatment based on estimate of average patient usage provided by IntrinsiQ intelliVIEW™. Total number of vials from November 2010 to March 2020.

DOWNLOAD THIS NURSE BROCHURE AND ACCESS ADDITIONAL RESOURCES AT **WWW.HALAVEN.COM/HCP/METASTATIC-BREAST-CANCER**

Selected Safety Information

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.

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

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

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