Introducing HALAVEN®

1. HALAVEN® is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. [1]
2. HALAVEN® is indicated for the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease. [1]

Composition[1]

Each vial (2 ml) contains 1.0 mg of eribulin mesylate, equivalent to 0.88 mg of eribulin.

Administration[1]

HALAVEN® is a sterile, clear and colourless aqueous solution of eribulin for intravenous administration. It may be administered undiluted or diluted.

To administer undiluted, aseptically withdraw from vial.

To administer diluted aseptically withdraw, then dilute in up to 100 mL of 0.9% sodium chloride injection.

Storage[1]

HALAVEN® should be stored below 25°C.

	Temperature (25°C) and ambient lighting	Refrigeration (2-8°C)
Undiluted HALAVEN®	4 hours	24 hours
Diluted HALAVEN® (0.02 mg/ml to 0.2 mg/ml in sodium chloride 9 mg/ml (0.9%) solution for injection)	–	≤ 24 hours maximum*

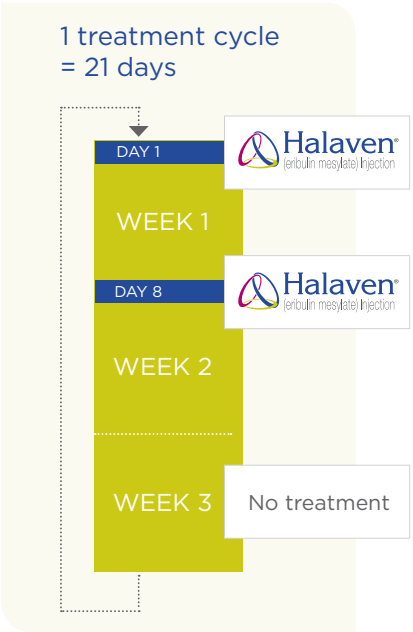
*unless dilution has taken place in controlled and validated aseptic conditions.

Halaven®
(eribulin mesylate) Injection

MORE THAN JUST SURVIVAL

Posology[1]

The recommended dose of eribulin mesylate as the ready to use solution is 1.4 mg/m^2 (equivalent to 1.23 mg/m^2 eribulin) which should be administered intravenously over 2 to 5 minutes on Days 1 and 8 of every 21-day cycle.



Dose reduction for specific populations[1]

Mild hepatic impairment: 1.1 mg/m^2

Moderate hepatic impairment: 0.7 mg/m^2

Dose delays during therapy[1]

The administration of HALAVEN® should be delayed on Day 1 or Day 8 for any of the following:

-Absolute neutrophil count (ANC) <1 X 10^9/L

-Platelets <75 X 10^9/L

-Grade 3 or 4 non-haematological toxicities

Dose reduction recommendations[1]

Adverse reaction after previous HALAVEN® administration	Recommended dose
Haematological:	1.1 mg/m^2
ANC < 0.5 x 10^9/l lasting more than 7 days	
ANC < 1 x 10^9/l neutropenia complicated by fever or infection	
Platelets < 25 x 10^9/l thrombocytopenia	
Platelets < 50 x 10^9/l thrombocytopenia complicated by haemorrhage or requiring blood or platelet transfusion	
Non-Haematological:	
Any Grade 3 or 4 in the previous cycle	
Recurrence of any haematological or non-Haematological adverse reactions as specified above:	0.7 mg/m^2
Despite reduction to 1.1 mg/m^2	
Despite reduction to 0.7 mg/m^2	Consider discontinuation

The dose of HALAVEN® should not be re-escalated after it has been reduced.

REFERENCE: 1. HALAVEN® Prescribing Information (approved 31 May 2019).

Abbreviated Prescribing Information

Composition: One ml contains 0.5 mg of eribulin mesylate, equivalent to 0.44 mg of eribulin. Each vial (2 ml) contains 1.0 mg of eribulin mesylate, equivalent to 0.88 mg of eribulin. **Pharmacology:** HALAVEN® (eribulin mesylate) is a microtubule dynamics inhibitor belonging to the halichondrin class of antineoplastic agents. It is a structurally simplified synthetic analogue of halichondrin B, a natural product isolated from the marine sponge Halichondria okadai. Eribulin inhibits the growth phase of microtubules without affecting the shortening phase and sequesters tubulin into non-productive aggregates. Eribulin exerts its effects via a tubulin-based antimitotic mechanism leading to G2/M cell-cycle block, disruption of mitotic spindles, and, ultimately, apoptotic cell death after prolonged and irreversible mitotic blockage. In addition, eribulin treatment of human breast cancer cells caused changes in morphology and gene expression as well as decreased migration and invasiveness in vitro. In mouse xenograft models of human breast cancer, eribulin treatment was associated with increased vascular perfusion and permeability in the tumor cores, resulting in reduced tumor hypoxia, and changes in the expression of genes in tumor specimens associated with a change in phenotype. **Indication:** HALAVEN® is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. HALAVEN® is indicated for the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease. **Dose and Administration:** The recommended dose of eribulin mesylate as the ready to use solution is 1.4 mg/m^2 (equivalent to 1.23 mg/m^2 eribulin) which should be administered intravenously over 2 to 5 minutes on Days 1 and 8 of every 21-day cycle. **Precautions:** Myelosuppression is dose dependent and primarily manifested as neutropenia. Monitoring of complete blood counts should be performed on all patients prior to each dose of eribulin. Treatment with eribulin should only be initiated in patients with ANC values 1.5 x 10^9/l and platelets > 100 x 10^9/l. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients, breast feeding. **Warning:** Haematology, peripheral neuropathy, QT prolongations. **Drug interaction:** Caution and monitoring for adverse events is recommended with concomitant use of substances that have a narrow therapeutic window and that are eliminated mainly via CYP3A4-mediated metabolism (e.g. alfentanil, cyclosporine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus). **Adverse reactions:** Neutropenia (53.6%), leukopenia (27.9%), anaemia (21.8%), peripheral neuropathy (35.9%), nausea (35.7%), fatigue/astenia (53.2%). **Storage:** Store below 25°C.

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา

For healthcare professionals only
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