

PATIENT INFORMATION
HALAVEN® (HAL-ih-ven)
(eribulin mesylate)
injection, for intravenous use

What is the most important information I should know about HALAVEN?

HALAVEN can cause serious side effects, including:

- **Low white blood cell count (neutropenia).** This can lead to serious infections that could lead to death. Your healthcare provider will check your blood cell counts before you receive each dose of HALAVEN and during treatment. Call your healthcare provider right away if you develop any of these symptoms of infection:
 - fever (temperature above 100.5°F)
 - chills
 - cough
 - burning or pain when you urinate
- **Numbness, tingling, or pain in your hands or feet (peripheral neuropathy).** Peripheral neuropathy is common with HALAVEN and sometimes can be severe. Tell your healthcare provider if you have new or worsening symptoms of peripheral neuropathy.
- Your healthcare provider may delay, decrease your dose, or stop treatment with HALAVEN if you have side effects.

See “**What are possible side effects of HALAVEN?**” for more information about side effects.

What is HALAVEN?

HALAVEN is a prescription medicine used to treat people with:

- Breast cancer
 - that has spread to other parts of the body, **and**
 - who have already received certain types of anticancer medicines after the cancer has spread
- Liposarcoma
 - that cannot be treated with surgery or has spread to other parts of the body, **and**
 - who have received treatment with a certain type of anticancer medicine

It is not known if HALAVEN is safe and effective in children under 18 years of age.

Before you receive HALAVEN, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have heart problems, including a problem called congenital long QT syndrome
- have low potassium or low magnesium in your blood
- are pregnant or plan to become pregnant. HALAVEN can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with HALAVEN.
 - **Females** who are able to become pregnant should use an effective birth control during treatment with HALAVEN and for at least 2 weeks after the final dose of HALAVEN.
 - **Males** should use an effective form of birth control when having sex with female partners who are able to become pregnant during treatment with HALAVEN and for 3 1/2 months (14 weeks) after the final dose of HALAVEN.
- are breastfeeding or plan to breastfeed. It is not known if HALAVEN passes into your breast milk. Do not breastfeed during treatment with HALAVEN and for 2 weeks after the final dose of HALAVEN.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive HALAVEN?

- HALAVEN is given by intravenous (IV) injection in your vein.
- HALAVEN is given in “cycles” of treatment, with each cycle lasting 21 days.
- HALAVEN is usually given on day 1 and day 8 of a treatment cycle.

What are the possible side effects of HALAVEN?

HALAVEN may cause serious side effects, including:

- See “**What is the most important information I should know about HALAVEN?**”
- **HALAVEN can cause changes in your heartbeat (called QT prolongation).** This can cause irregular heartbeats. Your healthcare provider may do heart monitoring (electrocardiogram or ECG) or blood tests during your treatment with HALAVEN to check for heart problems.

The most common side effects of HALAVEN in people with breast cancer include:

- low white blood cell count (neutropenia)
- low red blood cell count (anemia)
- weakness or tiredness
- hair loss (alopecia)
- nausea
- constipation

The most common side effects of HALAVEN in people with liposarcoma include:

- tiredness
- nausea
- hair loss (alopecia)
- constipation
- stomach pain
- fever

Your healthcare provider will do blood tests before and during treatment while you are taking HALAVEN. The most common changes to blood tests in people with liposarcoma include:

- low white blood cell count (neutropenia)
- decreased blood levels of potassium or calcium

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of HALAVEN. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about HALAVEN

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about HALAVEN that is written for health professionals.

What are the ingredients in HALAVEN?

Active Ingredient: eribulin mesylate

Inactive Ingredients: dehydrated alcohol, water for injection, and sodium hydroxide or hydrochloric acid may be used for pH adjustment.

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Distributed by: Eisai Inc. Nutley, NJ 07110

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For more information, go to www.HALAVEN.com or call Eisai Inc. at 1-877-873-4724. If you would like a leaflet with larger printing, please contact Eisai Inc. at 1-877-873-4724.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 09/2022