

Tips for the Management of Common Side Effects of HALAVEN®

These are some of the most common side effects of HALAVEN and some tips for management that may help. The full list of side effects can be found in the accompanying Patient Information or by visiting www.halaven.com for additional information. Before you receive HALAVEN, tell your health care provider about all of your medical conditions. Always tell your health care team about any side effects that you are experiencing.



Numbness, tingling, or pain in your hands or feet

(peripheral neuropathy)



- Avoid hot baths and drinking alcohol, which may worsen these symptoms
- Avoid cold temperatures. Wear gloves and socks
- Practice low-intensity activities (yoga, walking), as discussed with your health care provider
- Be careful when handling sharp objects
- If you have diabetes, control your blood sugar levels as high blood sugar can damage nerves

Low white blood cell count

(neutropenia)



- Practice good hand hygiene
- Maintain good mouth care, and consider a mouth rinse with salt or baking soda and salt
- Keep cuts or scrapes clean and covered
- Avoid sources of potential bacterial infections (hot tubs, rivers) and eating unpasteurized dairy or undercooked meat
- Avoid contact with sick people or touching human or animal waste

Who is HALAVEN (eribulin mesylate) Injection for?

HALAVEN is a prescription medicine used to treat adults with breast cancer that has spread to other parts of the body, and who have already received other types of anticancer medicines after the cancer has spread.

Important Safety Information

What safety information do I need to 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 health care provider will check your blood cell counts. Call your health care provider right away if you develop fever (temperature above 100.5°F), chills, cough, or burning or pain when you urinate, as any of these can be symptoms of infection
- **Numbness, tingling, or pain in your hands or feet (peripheral neuropathy).** Peripheral neuropathy is common with HALAVEN and sometimes can be severe. Tell your health care provider if you have new or worsening symptoms of peripheral neuropathy
- Your health care provider may delay or decrease your dose or stop treatment with HALAVEN if you have side effects

Before you receive HALAVEN, tell your health care 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 health care 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 form of birth control during treatment with HALAVEN and for at least 2 weeks after the final dose of HALAVEN and 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 3½ 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

Please see additional Important Safety Information on reverse side and accompanying Patient Information.

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

Hair loss

(alopecia)



- To help prevent or reduce hair loss/thinning, avoid harsh products for your hair or scalp. Try using mild shampoo and soft brushes
- Avoid using items that might damage your hair (dyes, sprays, or hair bands and clips)
- Decrease frequency of hair washing
- Consider changing your hairstyle before a potential hair loss

Nausea



- Limit portion size and eat several small meals instead of 3 large meals. Choose easy-to-digest food and drinks:
 - Increase fruit and vegetable intake
 - Limit high-fat products (mayonnaise, butter)
- Avoid fried and spicy food
- Sip water at room temperature all day long, unless your doctor instructs you to limit fluid intake
- Sip flat ginger ale or ginger tea

Feeling very tired

(fatigue)



- Try to stay active by getting regular exercise (with your health care provider's approval)
- Drink plenty of water as tolerated (unless instructed otherwise by your doctor)
- Eat healthy meals to give you more energy
- Plan rest time in your daily schedule, and ask for help with difficult daily tasks or chores
- Consider mental health counseling, stress management, and relaxation exercises to improve the feelings related to fatigue



Check out the HALAVEN® community on Facebook at www.facebook.com/halaven



Additional information, patient communities, and other support groups can be found at www.halaven.com

During your next visit, let your health care provider know if you have any questions and/or new or worsening symptoms

Write down any questions or symptoms you are currently experiencing here so that you can share them with your health care provider.

Important Safety Information, Continued

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

What are the possible side effects of HALAVEN?

HALAVEN can cause changes in your heartbeat (called QT prolongation). This can cause irregular heartbeats. Your health care 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 adults with breast cancer include low white blood cell count (neutropenia), low red blood cell count (anemia), weakness or tiredness, hair loss (alopecia), nausea, and constipation.

Your health care provider will do blood tests before and during treatment while you are taking HALAVEN.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see additional Important Safety Information on reverse side and accompanying Patient Information.



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

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: ethanol, water

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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.

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