

Package leaflet: Information for the user

HALAVEN 0.44 mg/ml solution for injection eribulin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What HALAVEN is and what it is used for
2. What you need to know before you use HALAVEN
3. How to use HALAVEN
4. Possible side effects
5. How to store HALAVEN
6. Contents of the pack and other information

1. What HALAVEN is and what it is used for

HALAVEN contains the active substance eribulin and is an anti-cancer medicine which works by stopping the growth and spread of cancer cells.

It is used in adults for locally advanced or metastatic breast cancer (breast cancer that has spread beyond the original tumour) when at least one other therapy has been tried but has lost its effect.

It is also used in adults for advanced or metastatic liposarcoma (a type of cancer that arises from fat tissue) when previous therapy has been tried but has lost its effect.

2. What you need to know before you use HALAVEN

Do not use HALAVEN:

- if you are allergic to eribulin mesilate or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding

Warnings and precautions

Talk to your doctor or nurse before using HALAVEN:

- if you have liver problems
- if you have a fever or an infection
- if you experience numbness, tingling, prickling sensations, sensitivity to touch or muscle weakness
- if you have heart problems

If any of these affects you, tell your doctor who may wish to stop treatment or reduce the dose.

Children and adolescents

Halaven is not recommended for children aged under 18 with paediatric sarcomas as it is not yet known how well it works in this age group.

Other medicines and HALAVEN

Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

HALAVEN may cause serious birth defects and should not be used if you are pregnant unless it is thought clearly necessary after carefully considering all the risk to you and the baby. It may also cause future permanent fertility problems in men if they take it and they should discuss this with their doctor before starting treatment. Women of childbearing age should use effective contraception during and up to 3 months after treatment with HALAVEN.

HALAVEN must not be used during breast-feeding because of the possibility of risk to the child.

Driving and using machines

HALAVEN may cause side effects such as tiredness (very common) and dizziness (common). Do not drive or use machines if you feel tired or dizzy.

HALAVEN contains ethanol (alcohol)

This medicine contains small amounts of ethanol (alcohol), less than 100 mg in a vial.

3. How to use HALAVEN

HALAVEN will be given to you by a doctor or nurse as an injection into a vein, over a period of 2 to 5 minutes. The dose you will receive is based on your body surface area (expressed in squared metres, or m²) which is calculated from your weight and height. The usual dose of HALAVEN is 1.23 mg/m², but this may be adjusted by your doctor based on your blood test results or other factors. To ensure that the whole dose of HALAVEN is given it is recommended that a saline solution is flushed into the vein after HALAVEN is given.

How often will you be given HALAVEN?

HALAVEN is usually given on Days 1 and 8 of every 21-day cycle. Your doctor will determine how many cycles of treatment you should receive. Depending on the results of your blood tests, the doctor may need to delay administration of the medicine until the blood tests return to normal. The doctor may also then decide to reduce the dose you are given.

If you have any further questions about the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious symptoms, stop taking HALAVEN and seek medical attention straightaway:

- Fever, with a racing heart beat, rapid shallow breathing, cold, pale, clammy or mottled skin and/or confusion. These may be signs of a condition called sepsis – a severe and serious reaction to an infection. Sepsis is uncommon (may affect up to 1 in 100 people) and can be life-threatening and may result in death.
- Any difficulty breathing, or swelling of your face, mouth, tongue or throat. These could be signs of an uncommon allergic reaction (may affect up to 1 in 100 people).
- Serious skin rashes with blistering of the skin, mouth, eyes and genitals. These may be signs of a condition called Stevens Johnson syndrome/toxic epidermal necrolysis. The frequency of this condition is not known but it can be life-threatening.

Other side effects:

Very common side effects (may affect more than 1 in 10 people) are:

- Decrease in the number of white blood cells or red blood cells
- Tiredness or weakness
- Nausea, vomiting, constipation, diarrhoea
- Numbness, tingling or prickling sensations
- Fever
- Loss of appetite, weight loss
- Difficulty breathing, cough
- Pain in the joints, muscles and back
- Headache
- Hair loss

Common side effects (may affect up to 1 in 10 people) are:

- Decrease in the number of platelets (which may result in bruising or taking longer to stop bleeding)
- Infection with fever, pneumonia, chills
- Fast heart rate, flushing
- Vertigo, dizziness
- Increased production of tears, conjunctivitis (redness and soreness of the surface of the eye), nosebleed
- Dehydration, dry mouth, cold sores, oral thrush, indigestion, heartburn, abdominal pain or swelling
- Swelling of soft tissues, pains (in particular chest, back and bone pain), muscle spasm or weakness
- Mouth, respiratory and urinary tract infections, painful urination
- Sore throat, sore or runny nose, flu-like symptoms, throat pain
- Liver function test abnormalities, altered level of sugar, bilirubin, phosphates, potassium, magnesium or calcium in the blood
- Inability to sleep, depression, changed sense of taste
- Rash, itching, nail problems, dry or red skin
- Excessive sweating (including night sweats)
- Ringing in the ears
- Blood clots in the lungs
- Shingles
- Swelling of the skin and numbness of the hands and feet

Uncommon side effects (may affect up to 1 in 100 people) are:

- Blood clots
- Abnormal liver function tests (hepatotoxicity)
- Kidney failure, blood or protein in the urine
- Widespread inflammation of the lungs which may lead to scarring
- Inflammation of the pancreas
- Mouth ulcers

Rare side effects (may affect up to 1 in 1000 people) are:

- A serious disorder of blood clotting resulting in the widespread formation of blood clots and internal bleeding.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store HALAVEN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the vial after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What HALAVEN contains

- The active substance is eribulin. Each 2 ml vial contains eribulin mesilate equivalent to 0.88 mg eribulin. Each 3 ml vial contains eribulin mesilate equivalent to 1.32 mg eribulin.
- The other ingredients are ethanol and water for injections, with hydrochloric acid and sodium hydroxide possibly present in very small amounts.

What HALAVEN looks like and contents of the pack

HALAVEN is a clear, colourless aqueous solution for injection provided in glass vials containing 2 ml or 3ml of solution. Each carton contains either 1 or 6 vials.

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>