

Halaven®

Eribulin mesilate solution for injection (erib-u-lin)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Halaven.

It does not contain all the available information about HALAVEN. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

WHAT HALAVEN IS USED FOR

HALAVEN contains the active ingredient eribulin mesilate.

HALAVEN belongs to a group of medicines called Anti-cancer agents. It works by stopping the growth and spread of cancer cells.

HALAVEN is used for the treatment of breast cancer. It is used when at least one other therapy for locally advanced or metastatic breast cancer (i.e.; breast cancer that has spread beyond the original tumour) 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

BEFORE YOU TAKE HALAVEN

When you must not take it

Do not use HALAVEN

- If you are allergic (hypersensitive) to eribulin mesilate or any of the other ingredients of HALAVEN. Some of the - symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin
- If you are breast feeding

Before you start to take it

Take special care with HALAVEN

- If you have liver or kidney 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Please tell your doctor, if you are taking or have recently taken any other medicines, including herbal supplements and medicines obtained without a prescription.

Pregnancy and breast feeding

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 risks to you and the baby. It may also cause future 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 should not be used during breast feeding because of the possibility of risk to the child.

Important information about some of the ingredients of HALAVEN

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW HALAVEN IS GIVEN

HALAVEN will be given to you by a doctor or nurse as an injection into a vein, usually over a period of 2-5 minutes, but this may take longer. 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 1.4mg/m², but this may be adjusted by your doctor based on your blood test results or other factors.

How often will you be given HALAVEN?

HALAVEN is usually given on Days 1 and 8 of every 21-day cycle. 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. Your doctor will determine how many cycles of treatment you should receive.

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

WHILE YOU ARE TAKING HALAVEN

Things you must do

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking HALAVEN, tell your doctor immediately.

Things you must not do

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how HALAVEN affects you. HALAVEN may cause side effects such as tiredness (very common) and dizziness (common).

Do not drive or use machinery if you feel tired or dizzy.

SIDE EFFECTS

All medicines may have unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If you experience any of the following uncommon but 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 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 allergic reaction.

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
- Nausea, vomiting, constipation, diarrhoea
- Tiredness or weakness
- Fever
- Loss of appetite, weight loss
- Pain in the joints, muscles, back or limb extremities
- Numbness, tingling or prickling sensations in the ends of your limbs
- Headache
- Hair loss
- Difficulty breathing, cough

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) or lymphocytes (based on blood tests)
- Infection with fever, chills, pneumonia
- Fast heart rate, flushing
- Vertigo, dizziness
- Increased production of tears, conjunctivitis (redness and soreness of the surface of the eye), nose bleeds
- Dehydration, dry mouth, oral thrush, cold sores, indigestion, heartburn, abdominal pain or swelling
- Swelling of soft tissues or mucosal tissues, pains, (in particular chest, back and bone pain), muscle spasm or weakness
- Mouth, respiratory and urinary tract infections, painful urination.
- Sore throat, red, sore or runny nose, flu-like symptoms throat pain

- Liver function test abnormalities, altered level of sugar, bilirubin, phosphates, potassium, calcium or magnesium in the blood
- Abnormal sensations of touch
- Inability to sleep, depression, changed sense of taste
- Rash, itching, swelling and numbness of the hand and feet, nail problems, dry or red skin
- Excessive sweating (including night sweats)
- Ringing in the ears
- Blood clots in the lungs
- Shingles

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

- Severe infection with blood poisoning (sepsis)
- Blood clots
- Kidney failure, blood or protein in the urine
- Widespread inflammation of the lungs which may lead to scarring
- Inflammation of the pancreas
- Mouth ulcers
- Rapid swelling of an area of the skin

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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER RECEIVING HALAVEN

Storage

Keep out of reach and sight of children.

Do not use HALAVEN after the expiry date which is stated on the carton and the vial.

The expiry date refers to the last day of the month.

Store unopened vials below 25°C.

PRODUCT DESCRIPTION

What it looks like

HALAVEN is a clear, colourless aqueous solution for injection available in glass vials containing 2ml of solution (0.5 mg/ml)

Ingredients

Active ingredient:

- Eribulin mesilate

Excipient Ingredients:

- Ethanol
- Water for injections

SPONSOR

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