APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Halaven 0,44 mg/ml solution for injection

Eribulin

Please read all of this leaflet carefully before you are given Halaven

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Halaven has been prescribed for you personally and you should not share your medicines with other people. It may harm them, even if their symptoms are the same as yours.

WHAT HALAVEN CONTAINS

The active substance is eribulin. Each 2 ml vial contains 0,88 mg of eribulin (as mesilate). The other ingredients are 5 % (v/v) ethanol in water for injections.

Sugar free

WHAT HALAVEN IS USED FOR

Eribulin, the active ingredient of Halaven, is an anti-cancer agent 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.

BEFORE YOU ARE GIVEN HALAVEN

You should not be given Halaven

- if you are allergic (hypersensitive) to eribulin mesilate or any of the other ingredients of

Halaven

- if you are pregnant, planning to become pregnant or are breastfeeding your baby.

Tell your doctor or healthcare professional before being given the injection:

- if you have liver problems
- if you have 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. He/she may wish to stop treatment or reduce the dose.

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

Pregnancy and breastfeeding

Halaven may cause serious birth defects and should not be used if you are pregnant.

Halaven may also cause future permanent fertility problems if you are a man and you should discuss this with your doctor before starting treatment.

If you are a woman old enough to be able to have a baby, you should use effective contraception during and up to 3 months after your treatment with Halaven.

You should not breastfeed your baby while receiving Halaven because of the possible risk to your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before given Halaven.

Driving and using machinery

Halaven may cause side effects such as tiredness (very common) and dizziness (common). Do not drive or use machines when using Halaven.

Using other medicines with Halaven

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

HOW TO USE HALAVEN

Do not share medicines prescribed for you with any other person.

You will not be expected to administer Halaven yourself. It will be administered to you by a person who is qualified to do so.

Your doctor or nurse will give the Halaven as an injection into a vein, over a period of 2 to 5 minutes. The dose you receive will be decided 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. 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 Halaven 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 Halaven, ask your doctor.

POSSIBLE SIDE EFFECTS

Halaven can have side effects.

Not all side effects reported for Halaven are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Halaven, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Halaven and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Fever, especially if associated with a rapid heartbeat, 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 less frequent and can be life-threatening and may result in death.
- Any difficulty in breathing, or swelling of your face, mouth, tongue or throat. These could be signs of an allergic reaction.
- 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.

- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Halaven. You may need urgent medical attention or hospitalisation.

Other side effects:

Frequent side effects 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
- Difficult breathing, cough
- Pain in the joints, muscles and back
- Headache
- Hair loss
- 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, pain (particularly in chest, back and bone), 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, phosphates, potassium or magnesium in the blood

- Inability to sleep, depression, changed sense of taste
- Difficult breathing, cough, throat pain
- 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 (angioedema) and numbness of the hands and feet

Less frequent side effects 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
- A serious disorder of blood clotting resulting in the widespread formation of blood clots and internal bleeding

If any of the side effects get serious, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF HALAVEN

Store at or below 25 °C.

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

Discard any unused portion of the vial.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Store all medicines out of reach of children.

PRESENTATION OF HALAVEN

5 ml Type I clear glass vial, with teflon-coated, grey butyl rubber stopper and blue flip-off aluminium over seal, containing a sufficient volume to allow the withdrawal of 2 ml of solution.

The pack sizes are cartons of 1 or 6 vials.

Not all pack sizes may be marketed.

IDENTIFICATION OF HALAVEN

Clear, colourless aqueous solution for injection essentially free from visible particles of foreign matter.

REGISTRATION NUMBER

48/26/0047

NAME AND ADDRESS OF REGISTRATION HOLDER

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