PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

HALAVEN (solution for injection)

Eribulin

Each vial contains eribulin mesilate equivalent to 0,88 mg of eribulin in 2 ml of solution

Sugar free

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.

What is in this leaflet

1. What HALAVEN is and what it 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 a type of cancer that arises from fat tissue (liposarcoma) when previous therapy has been tried but has lost its effect.

2. What you need to know before you receive HALAVEN

HALAVEN should not be administered

- if you are allergic (hypersensitive) to eribulin mesilate or any of the other ingredients of HALAVEN (listed in Section 6).
- if you are pregnant, planning to become pregnant or are breastfeeding your baby.

Warnings and precautions

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.

Other medicines and HALAVEN

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

Pregnancy and breastfeeding and fertility

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 after your treatment with HALAVEN. You should continue for 7 months following your last dose of HALAVEN.

If you are a man receiving HALAVEN you should use effective contraception during and after your treatment with HALAVEN. You should continue for 4 months following your last dose of HALAVEN. If you are wishing to become a father in the future you should consider the possibility of freezing your sperm before you start treatment.

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.

3. 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.

If you receive more HALAVEN than you should

Since a healthcare provider will administer HALAVEN he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive HALAVEN

Since a healthcare provider will administer HALAVEN, it is unlikely that the dose will be forgotten.

4. 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 healthcare provider 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.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of HALAVEN.

5. How to store HALAVEN.

Store all medicines out of reach of children.

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.

If not used immediately, undiluted HALAVEN in a syringe should not be stored for longer than 4 hours at 25 oC under normal lighting or 24 hours at 2 °C – 8 °C.

Diluted solution should not be stored longer than 24 hours at 2 °C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Medicines should not be disposed 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.

6. Contents of the pack and other information

What HALAVEN contains

The active substance is eribulin (as eribulin mesilate)

The other ingredients are dehydrated alcohol, water for injection, hydrochloric acid and/or sodium hydroxide are used to adjust pH of the medicine during the compounding process if necessary.

What HALAVEN looks like and contents of the pack

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

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.

Holder of the Certificate of Registration

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An electronic copy of the Professional Information (PI) is available on the Eisai website

(http://www.eisai.co.za) or http://www.sahpra.org.za