

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ASPEN EPIRUBICIN 10 mg/5 ml (solution for injection)

ASPEN EPIRUBICIN 20 mg/10 ml (solution for injection)

ASPEN EPIRUBICIN 50 mg/25 ml (solution for injection)

ASPEN EPIRUBICIN 100 mg/50 ml (solution for injection)

ASPEN EPIRUBICIN 200 mg/100 ml (solution for injection)

Read all of this leaflet carefully before you start using/are given ASPEN EPIRUBICIN

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

WHAT ASPEN EPIRUBICIN CONTAINS

Each 5 ml solution of ASPEN EPIRUBICIN 10 mg/5 ml contains 10 mg of epirubicin hydrochloride (2 mg/ml)

Each 10 ml solution of ASPEN EPIRUBICIN 20 mg/10 ml contains 20 mg of epirubicin hydrochloride (2 mg/ml)

Each 25 ml solution of ASPEN EPIRUBICIN 50 mg/25 ml contains 50 mg of epirubicin hydrochloride (2 mg/ml)

Each 50 ml solution of ASPEN EPIRUBICIN 100 mg/50 ml contains 100 mg of epirubicin hydrochloride (2 mg/ml)

Each 100 ml solution of ASPEN EPIRUBICIN 200 mg/100 ml contains 200 mg of epirubicin hydrochloride (2 mg/ml)

The other ingredients are:

Water for injections

Sugar free

WHAT ASPEN EPIRUBICIN IS USED FOR

The active ingredient in ASPEN EPIRUBICIN belongs to the group of medicines (anthracyclines) known as antineoplastic agents (anti-cancer medicines).

ASPEN EPIRUBICIN is used to treat a variety of cancers, either alone or in combination with other medicines. The way in which it is used depends upon the type of cancer that is being treated.

When injected into the bloodstream, ASPEN EPIRUBICIN has been found to be useful in the treatment of cancers of the breast, ovaries, stomach, bowels and lung.

In addition ASPEN EPIRUBICIN can be given the same way to treat cancers of the blood forming tissues such as malignant lymphomas, leukaemias and multiple myeloma.

BEFORE YOU RECEIVE ASPEN EPIRUBICIN

You should not be administered ASPEN EPIRUBICIN:

- If you are hypersensitive (allergic) to epirubicin hydrochloride or any of the other ingredients of ASPEN EPIRUBICIN.
- If you are aware that your blood counts are too low, as ASPEN EPIRUBICIN can lower them further.
- If you have a mouth ulcer.
- If you have had, or currently have heart problems.
- If you have severe liver problems.
- If you are pregnant. If you are sexually active, you are advised to use effective birth control to prevent pregnancy during treatment.
- If you are breastfeeding.

Tell your doctor or healthcare provider before receiving ASPEN EPIRUBICIN:

Take special care with ASPEN EPIRUBICIN:

- If you are given medicines containing cimetidine.
- If your liver or kidneys are not working properly.
- Tell your doctor if you have recently received medicines containing daunorubicin, doxorubicin, idarubicin, mitoxantrone or radiation therapy as these may increase the risk of side effects involving the heart.
- If you are prescribed ASPEN EPIRUBICIN it should only be given to you by doctors or nurses experienced in giving chemotherapy.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby while receiving ASPEN EPIRUBICIN, please consult your doctor, pharmacist or other healthcare provider for advice.

ASPEN EPIRUBICIN may not be used at any time during pregnancy or whilst breastfeeding.

Taking/Giving/Using other medicines with ASPEN EPIRUBICIN

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Please inform your doctor or pharmacist

- if you are given medicines containing cimetidine - Cimetidine increases the time ASPEN EPIRUBICIN stays in the body.

HOW TO RECEIVE ASPEN EPIRUBICIN

Always receive ASPEN EPIRUBICIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

The usual dose is:

The dose of ASPEN EPIRUBICIN will be different for different patients. The dose that is used may depend on a number of things, including what the medicine is being used for, the patient's size, and whether or not other medicines are also being taken.

If you have any questions about the correct dose of ASPEN EPIRUBICIN, ask your doctor.

ASPEN EPIRUBICIN should be administered only by intravenous injection. It is not active

when given orally and should not be injected intramuscularly or intrathecally.

Your doctor will decide on the dose and number of day's treatment you receive depending on your condition and other treatment you may receive.

While one course of treatment may sometimes be enough, more often your doctor will advise further courses in three or four weeks time. It may take several courses before your illness is under control and you feel better.

Your doctor will tell you how long your treatment with ASPEN EPIRUBICIN will last.

If you have the impression that the effect of ASPEN EPIRUBICIN is too strong or too weak, tell your doctor or pharmacist.

If you receive more ASPEN EPIRUBICIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

You may notice sores in your mouth or the number of white blood cells and platelets (these help the blood to clot) in your blood may decrease. Should this happen, you may need antibiotics or blood transfusions. Mouth ulcers can be treated to make them less uncomfortable as they heal.

Heart damage can occur when high doses of ASPEN EPIRUBICIN are given. This may not be detected for several weeks so regular heart monitoring may be required for several weeks after your treatment has stopped.

If you forget/missed a dose of ASPEN EPIRUBICIN

You should receive your missed dose as soon as you remember, if within a few hours after missing a dose. Do not receive a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

ASPEN EPIRUBICIN can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- allergic reactions can occur as the medicine is given - you may feel feverish, short of breath with a tight chest or throat, or dizzy. If this happens, tell your doctor or nurse immediately.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

When you are receiving ASPEN EPIRUBICIN, if you feel pain, or a burning or stinging sensation at the place where the medicines goes into your vein you should tell your doctor immediately.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported but the frequency is unknown:

Between courses of treatment you may notice the following:

- Reddening of your urine, which is a normal occurrence related to the colour of the medicine, and should stop after a few days.
- Hair loss is common and may be quite severe. Beard growth may stop in men. Hair normally regrows when treatment course ends.
- Mouth ulcers can occur, and there may be a feeling of sickness (nausea), vomiting or diarrhoea.
- If you feel feverish, suffer chills or rashes it is important you tell your doctor, as you may be allergic to ASPEN EPIRUBICIN.
- Your doctor should test your blood count during treatment to detect anaemia (a low red blood cell count) that can leave you feeling tired and lethargic.
- White blood cell counts can also drop, increasing the chance of infections and a raised temperature or fever.
- Different blood components called platelets can be affected making you bruise more easily, or bleed more than usual if you hurt yourself. It is important to seek medical advice if this happens.
- The following side effects have been reported: low blood pressure, headaches, stopping of menstrual periods, hot flashes, increased levels of uric acid in the blood, kidney problems, eye problems, infection. Men may develop breasts.

When given in combination with other anti-cancer medicines, some patients have developed a secondary leukaemia after completing treatment. This is rare.

Your doctor will be making regular checks of

- Your blood to check for low blood cell counts that may need treatment.
- Your heart function, as ASPEN EPIRUBICIN can have effects upon this.
- Your liver using blood tests to check that ASPEN EPIRUBICIN is not affecting the way it functions in a harmful way.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ASPEN EPIRUBICIN

Store between 2 °C to 8 °C.

Protect from light.

Do not freeze.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ASPEN EPIRUBICIN

ASPEN EPIRUBICIN 10 mg/5 ml:

One Type I clear colourless glass vial, with a grey bromobutyl rubber stopper and an aluminium flip-off cap with a polypropylene disk.

ASPEN EPIRUBICIN 20 mg/10 ml:

One Type I clear colourless glass vial, with a grey bromobutyl rubber stopper and an

aluminium flip-off cap with a polypropylene disk.

ASPEN EPIRUBICIN 50 mg/25 ml:

One Type I clear colourless glass vial, with a grey bromobutyl rubber stopper and an aluminium flip-off cap with a polypropylene disk.

ASPEN EPIRUBICIN 100 mg/50 ml:

One Type I clear colourless glass vial, with a grey bromobutyl rubber stopper and an aluminium flip-off cap with a polypropylene disk.

ASPEN EPIRUBICIN 200 mg/100 ml:

One Type I clear colourless glass vial, with a grey bromobutyl rubber stopper and an aluminium flip-off cap with a polypropylene disk.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ASPEN EPIRUBICIN

Clear red solution, free of visible particulate matter.

REGISTRATION NUMBER

ASPEN EPIRUBICIN 10 mg/5 ml: 42/26/0528

ASPEN EPIRUBICIN 20 mg/10 ml: 42/26/0529

ASPEN EPIRUBICIN 50 mg/25 ml: 42/26/0530

ASPEN EPIRUBICIN 100 mg/50 ml: 42/26/0531

ASPEN EPIRUBICIN 200 mg/100 ml: 42/26/0532

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

DATE OF PUBLICATION

Date of registration: 12 June 2009

Date of the most recent amendment to the patient information leaflet as approved by the

Authority: 12 June 2009

Namibia: NS2

ASPEN EPIRUBICIN 50 mg/25 ml: 11/26/0003

ASPEN EPIRUBICIN 200 mg/100 ml: 11/26/0004

Botswana:

ASPEN EPIRUBICIN 50 mg/25 ml: BOT1502679 S2

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