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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DOXORUBICIN LIPOSOMAL 20 mg/10 ml ACCORD (Concentrate for solution for infusion)

DOXORUBICIN LIPOSOMAL 50 mg/25 ml ACCORD (Concentrate for solution for infusion)

Pegylated liposomal doxorubicin hydrochloride

Contains sugar: sucrose 100 mg/ml

Contains hydrogenated soy phosphatidylcholine (made from soyabean)

Read all of this leaflet carefully before you are given DOXORUBICIN LIPOSOMAL ACCORD

- 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

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1. What DOXORIBICIN LIPOSOMAL ACCOORD is and what it is used for

DOXORIBICIN LIPOSOMAL ACCOORD contains the active substance doxorubicin hydrochloride. It is used to treat different types of cancers, including breast, ovarian, skin cancer and cancer of the bone marrow.

2. What you need to know before you are given DOXORUBICIN LIPOSOMAL ACCORD

DOXORIBICIN LIPOSOMAL ACCOORD should not be administered:

- if you are hypersensitive (allergic) to doxorubicin, or any of the other ingredients of DOXORIBICIN LIPOSOMAL ACCOORD (listed in section 6)
- if you are pregnant or breastfeeding
- if you have AIDS-related skin cancer for which other therapies are available.
- If you are younger than 18 years old.

Warnings and precautions

Special care should be taken with DOXORUBICIN LIPOSOMAL ACCORD:

- if you have heart problems
- if you are already experiencing bone marrow suppression due to other cancer treatments or your HIV status
- if you have had your spleen removed.

DOXORIBICIN LIPOSOMAL ACCOORD can cause redness, swelling and blistering on the palms of the hands and soles of the feet. This is called hand-foot syndrome. Your doctor may prescribe Vitamin B6 and corticosteroids to prevent and treat this condition. Other techniques you can use to prevent and treat hand-foot syndrome are:

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- Keeping the hands and feet cool by exposing them to cool water (soaks, bath or swimming)
- Avoiding very hot water
- Avoid wearing gloves, socks or shoes that are too tight.

Other medicines and DOXORIBICIN LIPOSOMAL ACCOORD

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Tell your doctor if you are taking any other medicines to treat the cancer.

Pregnancy, breastfeeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.
- DOXORIBICIN LIPOSOMAL ACCOORD should not be used if you are pregnant or breastfeeding.
- If you are a woman of childbearing potential, use effective contraception during your treatment (or your partner's treatment) and for 6 months after.

Driving and using machines

- DOXORIBICIN LIPOSOMAL ACCOORD may make you feel dizzy or sleepy. If this happens do not drive or use machinery.
- It is not always possible to predict to what extent DOXORIBICIN LIPOSOMAL ACCOORD may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DOXORIBICIN LIPOSOMAL ACCOORD

affects you.

DOXORIBICIN LIPOSOMAL ACCOORD contains hydrogenated soy phosphatidylcholine.

This is made from soyabean. If you are allergic to peanuts or soya you should not be given DOXORUBICIN LIPOSOMAL ACCORD.

DOXORIBICIN LIPOSOMAL ACCOORD contains sucrose

If you are a diabetic patient, you may have to adjust your diabetic medication because of the sugar content in this medicine.

3. How DOXORIBICIN LIPOSOMAL ACCOORD will be given to you

- You will not be expected to give yourself DOXORUBICIN LIPOSOMAL ACCORD. It will be given to you by a person qualified to do so.
- Your doctor will tell you how long your treatment with DOXORIBICIN LIPOSOMAL ACCOORD will last. If you have the impression that the effect of this medicine is too strong or too weak, tell your doctor or pharmacist.
- DOXORIBICIN LIPOSOMAL ACCOORD will be administered to you as an infusion into your vein. It may take from 30 to 90 minutes to administer.
- Your doctor will determine the appropriate dose of DOXORIBICIN LIPOSOMAL ACCOORD to administer to you.

If you receive more DOXORIBICIN LIPOSOMAL ACCOORD than you should

Since a healthcare professional will administer DOXORUBICIN LIPOSOMAL ACCORD, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of DOXORUBICIN LIPOSOMAL ACCORD

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Since a healthcare provider will administer DOXORUBICIN LIPOSOMAL ACCORD, it is unlikely that a dose will be missed.

4. Possible side effects

- DOXORIBICIN LIPOSOMAL ACCOORD can have side effects.
- Not all side effects reported for DOXORIBICIN LIPOSOMAL ACCOORD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DOXORUBICIN LIPOSOMAL ACCORD, please consult your doctor, pharmacist or other healthcare professional for advice.
- If any of the following happens, DOXORIBICIN LIPOSOMAL ACCOORD should be stopped, tell your doctor immediately or go to the casualty department at your nearest hospital:
    - swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty swallowing or breathing
    - itching of the skin and rash
    - sweating, fever, shivering, chills
    - convulsions

These are all very serious side effects. If you have them, you may have had a serious reaction to DOXORUBICIN LIPOSOMAL ACCORD. 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:
    - Redness and swelling on hands and feet, which are tender and painful, blistering
    - Redness, swelling, stinging or tenderness at the injection site.
    - Unexplained bruising or abnormal bleeding which may indicate a blood abnormality

- Fever, chills, cough, shivering which may indicate an infection
- Change in heart rate, chest pain, shortness of breath, which may indicate a heart problem

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

- Tell your doctor if you notice any of the following:
  - Frequent side effects
    - White patches on the inner cheeks, tongue, roof of the mouth, and throat
    - Painful blisters on your torso
    - Fever, mouth sores, fatigue, swollen lymph glands (may indicate changes in your blood cells)
    - Decreased appetite
    - Feeling confused, anxious, depressed and experiencing difficulty sleeping.
    - Tingling sensation in hands and feet, headache, change in taste
    - Feeling lethargic, dizzy, stiffness of arms and legs
    - Eye infections
    - Rapid heart rate
    - Low or high blood pressure, flushing
    - Cough, nose bleeds
    - Nausea, vomiting, diarrhoea, constipation, stomach pain or discomfort, dry mouth
    - Dry skin, itchy skin
    - Darkened patches on skin, excessive sweating
    - Muscle pain or spasms, joint or bone pain
    - Pain on urination
    - Fever, fatigue, weakness

- Decreased weight

- Less frequent side effects or frequency unknown
  - Cold sores
  - Feeling faint, sleepy
  - Blurred vision, increased tear production
  - Feeling faint when standing up suddenly
  - Asthma, tightness in throat
  - Flatulence, gum disease, ulcers on lips, inflammation of the tongue
  - Acne, skin rash, changes to your nails, like spots, discoloration, nail separation
  - Breast pain, itchy or burning vagina or scrotum
  - Radiation recall, where the skin may look like a severe sunburn and may blister, peel, and become red, swollen, and painful.

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DOXORUBICIN LIPOSOMAL ACCORD.

5. How DOXORIBICIN LIPOSOMAL ACCOORD is stored

- Store all medicines out of reach of children.

- Store in a refrigerator (2 °C – 8 °C). Do not freeze.
- Store in the original package.

6. Contents of the pack and other information

What DOXORIBICIN LIPOSOMAL ACCOORD contains

- The active substance is pegylated liposomal doxorubicin hydrochloride.
- Each vial contains 2 mg/ml doxorubicin hydrochloride and delivers 10 ml (20 mg) or 25 ml (50 mg) in a concentrate for infusion.
- The other ingredients are: hydrogenated soy phosphatidylcholine, N-(carbonyl-methoxypolyethylene glycol-2000)-1,2-distearoyl-sn-glycero3 phosphoethanolamine, sodium salt (MPEG-DSPE), cholesterol, ammonium sulphate, histidine, sucrose, ethanol anhydrous, hydrochloric acid, concentrated, sodium hydroxide and water for injection.

What DOXORIBICIN LIPOSOMAL ACCOORD looks like and contents of the pack

- DOXORIBICIN LIPOSOMAL ACCOORD is a translucent red coloured dispersion filled in a clear glass vial. When examined under suitable conditions of visibility it should be practically free from particles.
- DOXORIBICIN LIPOSOMAL ACCOORD 20 mg/10 ml: 10 ml clear tubular glass vial (type I) with a 20 mm grey bromobutyl rubber stopper and a 20 mm aluminium blue coloured flip off seal.
- DOXORIBICIN LIPOSOMAL ACCOORD 50 mg/25 ml: 30 ml clear moulded glass vial (type I) with a 20 mm grey bromobutyl rubber stopper and a 20 mm aluminium red coloured flip off seal.

Pack sizes: single vial or packs of ten. (Not all pack sizes may be marketed)

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HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Building 31, Woodlands Office Park

20 Woodlands Drive

Woodmead

Johannesburg

South Africa

This leaflet was last revised in

08 July 2025

Registration number/s

DOXORUBICIN LIPOSOMAL 20 mg/10 ml ACCORD: 58/26/0248

DOXORUBICIN LIPOSOMAL 50 mg/25 ml ACCORD: 58/26/0249

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