Final Patient Information Leaflet

Read all of this leaflet carefully before Rubexet is administered to you.

- Keep this leaflet. You may need to read it again.
- It contains information on **Rubexet** which is part of your hospital treatment.
- If you have further questions, please ask your doctor or your nurse.

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

Rubexet 200 mg/100 ml (concentrate solution for dilution for IV infusion)

Rubexet 50 mg/25 ml (concentrate solution for dilution for IV infusion)

Rubexet 10 mg/5 ml (concentrate solution for dilution for IV infusion)

1. WHAT RUBEXET INJECTION CONTAINS:

The active substance is doxorubicin hydrochloride.

Rubexet 10 mg/5 ml: Each vial contains 2 mg of doxorubicin hydrochloride per ml.

Rubexet 50 mg/25 ml: Each vial contains 2 mg of doxorubicin hydrochloride per ml.

Rubexet 200 mg/100 ml: Each vial contains 2 mg of doxorubicin hydrochloride per ml.

THE OTHER INGREDIENTS ARE:

- Hydrochloric acid
- Nitrogen
- Sodium chloride
- Water for injection.

2. WHAT RUBEXET IS USED FOR:

Rubexet is one of a group of medicines known as anthracyclines. It works by killing tumour and blood cancer cells. Your doctor will be able to explain how doxorubicin might help in your particular condition.

3. BEFORE YOU RECEIVE RUBEXET :

You should not receive Rubexet:

- If you are allergic to its components or to doxorubicin hydrochloride (see What Rubexet Contains).
- If you are pregnant or breastfeeding (see Pregnancy and Lactation).
- If you suffer from heart disease.

Take special care with RUBEXET INJECTION:

Rubexet will only be used in specialised departments of oncology (cancer) and will be administered under the supervision of an experienced/qualified oncologist (doctor who treats cancer) who has specialised in the administration of anti-cancer medicines.

- Avoid any contact with your skin and mucous membranes.
- Tell your doctor if you suffer from liver disease.
- Tell your doctor if you suffer from ulceration of the mouth.
- Tell your doctor if you have secondary acute myelogenous leukaemia (AML), a type of cancer of the blood cells
- You may experience changes in your menstrual cycle and your ability to conceive may be affected.

Site of administration:

- Tell your doctor as soon as you experience stinging or redness at the site of injection. The infusion will immediately be stopped and restarted in another vein.
- Skin reactions due to previous cancer therapy may recur with administration of Rubexet.

- Rubexet irritates the skin and thrombophlebitis (inflammation of the vein with formation of a clot) and streaking of the skin over the vein used for infusion may occur and it should not be confused with extravasation (stinging or burning at injection site).

Cardiac risk with administration of Rubexet:

Rubexet may produce toxicity of the heart. This may result in a:

- Disturbance of cardiac function marked by ECG (picture of the electrical action of the heart) abnormalities
- Dysrhythmias (irregular heart beat)
- Delayed, sometimes fatal, chronic congestive heart failure (heart failure resulting in fluid build-up in the lungs and other body tissues).

Severe toxicity is more likely to occur if you are receiving increased doses and may occur months or even years after administration.

If you are on this treatment:

- You will undergo frequent ECG monitoring
- If your doctor finds any abnormalities he will discontinue treatment or do further evaluation tests.

Myelosuppression with the administration of Rubexet:

You may suffer from myelosuppression (a reduction in bone marrow activity that leads to a lower concentration of platelets, red blood cells and white blood cells) due to:

- Pre-existing HIV status
- Certain medicines
- Any tumours which involve bone marrow.

Your doctor will conduct blood tests regularly to monitor your blood cells.

Pregnancy and Breastfeeding:

Your oncologist will not administer Rubexet if:

- You are pregnant or breastfeeding (see BEFORE YOU TAKE Rubexet)
- Doxorubicin crosses the placenta and is distributed into breast milk.
- If you are pregnant or breastfeeding your baby while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice before receiving **Rubexet**.

You should not receive Rubexet if you are pregnant or breastfeeding or planning to become pregnant.

Effect on the ability to drive and use machines:

- Nausea and vomiting may occur
- If you suffer from these adverse effects you should avoid driving and operating machinery while on therapy with this medicine.

Taking other medicines with Rubexet:

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

The following medicines may interact with **Rubexet:**

- Other cancer medicines
- Medicines for heart disease
- Medicines for thinning the blood, e.g. heparin

4. HOW RUBEXET WILL BE ADMINISTERED:

- Your oncologist will calculate your dosage according to your body surface area and the cancer to be treated.
- **Rubexet** will be administered intravenously (injected into a vein).
- The dose will be repeated at intervals determined by your doctor.
- Your doctor will tell you how long your treatment with **Rubexet** will last.
- If you have the impression that the effect of **Rubexet** is too str[i]ong or too weak, tell your doctor.
- You will not be expected to give yourself **Rubexet**. It will be given to you by a person who is qualified to do so.

If you receive more Rubexet than you should:

- Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
- The symptoms of overdosage will be an extension of the side effects. Please tell your doctor if you experience a worsening of any of the side effects.

5. POSSIBLE SIDE EFFECTS

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

- **If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:**
    - Swelling of the hands, feet, face, lips or throat, which may cause difficulty breathing
    - Rash or itching
    - Fainting

These are all serious side effects. If you have them you may have a serious allergic reaction to **Rubexet**. 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:**
    - Feeling tired and lethargic
    - Bleeding or bruising easily
    - Fever (raised temperature)
    - Infection
    - abnormal increase or irregular in heart rate
    - shortness of breath and swollen legs
    - pain and swelling at the injection site

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

- **Tell your doctor as soon as possible if you notice any of the following:**
    - feeling of nausea
    - vomiting
    - diarrhoea
    - swollen or sore mouth
    - stomach pain
    - passing of blood in stools
    - headache
    - eye infection
    - excessive secretion of tears
    - low blood pressure
    - cough or shortness of breath
    - jaundice (yellowing of skin and eyes)

- decreased urination
- absence of menstruation
- enlarged breasts
- reduced sperm volume

- **Tell your doctor if you notice any of the following:**
  - loss of hair
  - urine might appear red in colour

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

6. STORING AND DISPOSING OF RUBEXET:

Store at or below 2-8 °C.

Keep tightly closed.

Protect from light.

Keep out of reach of children.

Store in unit carton until required for use.

Do not freeze

Infusion preparation:

The medicinal product is for single use only. Any unused solution should be discarded.

After dilution with 0,9 % Sodium Chloride or Dextrose 5 % in water the diluted solution should be used immediately.

7. PRESENTATION OF RUBEXET:

Rubexet 10 mg/5 ml: concentrate solution for dilution for IV infusion is packaged in a 5 ml type I transparent clear glass vial, with a 20 mm teflon rubber stopper and a 20 mm aluminium flip-off pink seal.

Rubexet 50 mg/25 ml: concentrate solution for dilution for IV infusion is packaged in a 30 ml type I transparent clear glass vial, with a 20 mm teflon rubber stopper and a 20 mm aluminium flip-off pink seal.

Rubexet 200 mg/100 ml: concentrate solution for dilution for IV infusion is packaged in a 100 ml type I clear glass vial, with a 20 mm teflon rubber stopper and a 20 mm aluminium flip-off pink seal.

8. IDENTIFICATION OF RUBEXET:

Rubexet 10 mg/5 ml: A clear red solution, filled in clear glass vial when examined under suitable conditions of visibility it should be free from particles.

Rubexet 50 mg/25 ml: A clear red solution, filled in clear glass vial. When examined under suitable conditions of visibility it should be free from particles

Rubexet 200 mg/100 ml: A clear red solution, filled in a clear glass vial. When examined under suitable conditions of visibility it should be free from particles.

9. REGISTRATION NUMBER / REFERENCE NUMBER:

Rubexet 10 mg/5 ml: 46/26/0487

Rubexet 50 mg/25 ml: 46/26/0488

Rubexet 200 mg/100 ml: 46/26/0489

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Accord Healthcare (Pty) Ltd

Tuscany Office Park

6 Coombe Place

Rivonia, Gauteng

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11. DATE OF PUBLICATION:

To be allocated.