CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DOXORUBICIN-SOL PCH 10 mg, doxorubicin hydrochloride 2 mg/ml, Solution for Injection

DOXORUBICIN-SOL PCH 20 mg, doxorubicin hydrochloride 2 mg/ml, Solution for Injection

DOXORUBICIN-SOL PCH 50 mg, doxorubicin hydrochloride 2 mg/ml, Solution for Injection

DOXORUBICIN-SOL PCH 200 mg, doxorubicin hydrochloride 2 mg/ml, Solution for Injection

Read all of this leaflet carefully before you are given DOXORUBICIN-SOL PCH

- Keep this leaflet. You may need to read it again.

- If you have any further questions, please ask your doctor or pharmacist.

- DOXORUBICIN-SOL PCH 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.

1. WHAT DOXORUBICIN-SOL PCH CONTAINS

The active substance is doxorubicin hydrochloride 2 mg/ml.

The other ingredients are sodium chloride, and water for injection.

2. WHAT DOXORUBICIN-SOL PCH IS USED FOR

DOXORUBICIN-SOL PCH belongs to the group of medicines called cytotoxics used for chemotherapy. **DOXORUBICIN-SOL PCH** works by slowing or stopping the growth of cancer cells.

- It is used alone or in combination with other treatments/ medications to treat several different types of cancer.

- It can be used for treatment of the following types of cancers: Bladder, breast, ovarian, liver, stomach, prostate, head and neck, acute leukemia and uterus.

3. BEFORE DOXORUBICIN-SOL PCH IS ADMINISTERED TO YOU

You should not be administered DOXORUBICIN-SOL PCH :

- If you are hypersensitive (allergic) to doxorubicin or any of the other ingredients of **DOXORUBICIN-SOL PCH.**
- If the ability of your bone marrow to produce blood cells has decreased following exposure to cancer treatment.
- If you had previously received doxorubicin or other chemotherapy treatment in the same class as this might increase incident of side effects.
- If you are suffering or have suffered from heart problems and are currently receiving treatment for it.

Tell you doctor or healthcare professional before being given the injection if:

- you have received or are due to receive other anticancer medicines. You will need some time to recover from the effects of other anticancer medicines before you begin treatment with **DOXORUBICIN-SOL PCH.**
- you have had or are due for any vaccination.
- **DOXORUBICIN-SOL PCH** should only be used in specialized cancer departments and under the supervision of a doctor that specializes in cancer treatment.
- **DOXORUBICIN-SOL PCH** can temporarily lower the number of white and/or red blood cells, increasing the chance of getting an infection.

  This can lower your body's ability to fight infection and stop bleeding. Tell your doctor immediately if you develop any signs of infection (e.g., fever, chills, persistent sore throat), unusual tiredness, or

easy bleeding/bruising.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **DOXORUBICIN-SOL PCH**.

Driving and using machinery:

DOXORUBICIN-SOL PCH may cause some people to become nauseous and to have headaches. Do not drive or operate any machinery before you know how **DOXORUBICIN-SOL PCH** affects you.

Using other medicines with DOXORUBICIN-SOL PCH :

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

Let your doctor, pharmacist or other healthcare professional know if:

- You have recently received other cancer treatment;
- You are receiving or taking any medicine for your heart

4. HOW TO RECEIVE DOXORUBICIN-SOL PCH

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

Your medicine will be given to you by injection into a vein under the direction of your doctor.

The amount of **DOXORUBICIN-SOL PCH** you will receive depends on many factors, including your height and weight, your general health or other health problems, and the type of cancer you have. Your doctor will determine your exact dosage and schedule.

Your doctor will tell you how long your treatment with **DOXORUBICIN-SOL PCH** will last. Do

not stop treatment early. If you have the impression that the effect of **DOXORUBICIN-SOL PCH** is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself **DOXORUBICIN-SOL PCH.** It will be given to you by a person who is qualified to do so.

If you receive more DOXORUBICIN-SOL PCH 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.

If you missed a dose of DOXORUBICIN-SOL PCH:

Do not receive a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

DOXORUBICIN-SOL PCH can have side effects.

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

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

- Chest pains.
- Fever or chills – indicate possible signs of infection.
- Blistering at the place where the medicine was injected.
- Shortness of breath, wheezing, difficulty breathing, closing up of the throat, swelling of facial

features, hives – indication of possible allergic reaction.

- Unusual bleeding or bruising.
- Irregular heartbeat, swelling of ankles and severe shortness of breath may indicate heart problem even if they occur after the course ends.
- Bloody mucus or discharge in stools.

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

Tell your doctor if you notice any of the following:

- Red colouration of urine. This is related to the colour of the medicine, but inform your doctor if it does not clear in a few days.
- Nausea and vomiting.
- Temporary hair loss that resolves when treatment course ends, on the scalp and elsewhere on the body.
- Painful sores on the lips, mouth and throat. To decrease the risk, limit hot foods and drinks, brush your teeth carefully, avoid using mouthwash that contains alcohol, and rinse your mouth frequently with cool water.
- Darkening of the nail beds.
- Watering of the eyes.

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

6. STORING AND DISPOSING OF DOXORUBICIN-SOL PCH

Store all medicines out of reach of children.

Store between 2 – 8 ºC, protect from light. Do not freeze the vial.

Store in original package.

After dilution*:*

After dilution to a concentration of 0,5 mg/ml in 9 mg/ml (0,9 %) sodium chloride solution for infusion or in 50 mg/ml (5 %) glucose solution for infusion, the solution has been shown to be stable for 7 days when stored protected from light at 15 - 25 °C and 2 – 8 °C.

After dilution to the concentration of 0,05 mg/ml, the diluted solution should be used immediately.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF DOXORUBICIN-SOL PCH

DOXORUBICIN-SOL PCH 10 mg: 5 ml clear glass single dose vial.

DOXORUBICIN-SOL PCH 20 mg: 10 ml clear glass single dose vial

DOXORUBICIN-SOL PCH 50 mg: 25 ml clear glass single dose vial.

DOXORUBICIN-SOL PCH 200 mg: 100 ml clear glass multi-dose vial.

8. IDENTIFICATION OF DOXORUBICIN-SOL PCH

A clear red solution.

9. REGISTRATION NUMBER

DOXORUBICIN-SOL PCH 10 mg: Z/26/167

DOXORUBICIN-SOL PCH 20 mg: Z/26/168

DOXORUBICIN-SOL PCH 50 mg: Z/26/169

DOXORUBICIN-SOL PCH 200 mg: Z/26/170

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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