Epirubicin hydrochloride 2 mg/ml contains no preservatives and is therefore suitable for single use. After use the unused remainder should not be destroyed according to the regulations for cytostatic agents. See also “Disposal”.

Inactivation of spilled or leaking medicinal product can be obtained with a 1% sodium hypochlorite solution or simply with a surfactant buffer (pH 8-9) until the disinfection is dissolved.

Cleaning materials are disposed of as mentioned under “Disposal”.

Intravenous injections by the intravenous route are contraindicated in patients with cardiac side effects. Your cardiac function will be checked before treatment.

The gelled product will return to a slightly yellowish solution. For the treatment with a high dose epirubicin should be administered as an intravenous infusion over 3–5 minutes or as an infusion over 30 minutes (depending on the dose).

2. PRESENTATION

- Epirubicin hydrochloride 2 mg/ml in a 5 ml vial containing 2.1 mg Epirubicin hydrochloride
- Epirubicin hydrochloride vial: 2 mg/ml

8. ADVERSE REACTIONS

The following information is intended for physicians who are involved in the treatment or care of persons suffering from cancer, or their families.

- The medicines mentioned in this section may be known to you under a different name, often the brand name. In this section only the generic name is used.

- They have similar effects but may differ in some respects such as dose, administration route and frequency of administration.

- If you notice that Epirubicin hydrochloride 2 mg/ml is too strong or too weak, consult your doctor or pharmacist.

- Reporting of side effects includes any possible side effects not listed in this leaflet. See also “What to do if you think there is an allergic reaction”.

13. HOW YOU USE EPIRUBICIN HYDROCHLORIDE

Epirubicin hydrochloride 2 mg/ml contains no preservatives and is therefore suitable for single use. After use the unused remainder should not be destroyed according to the regulations for cytostatic agents. See also “Disposal”.

Inactivation of spilled or leaking medicinal product can be obtained with a 1% sodium hypochlorite solution or simply with a surfactant buffer (pH 8-9) until the disinfection is dissolved. Cleaning materials are disposed of as mentioned under “Disposal”.

Potential adverse effects include:
- Fever
- Irregular heartbeat
- Painful somewhat hard core with vascular inflammation with the possibility of forming blood clots
- Thrombocytopoenia
- Rare: Shock

- Nausea and vomiting often occur within the first 15 minutes after the injection. This can also be seen when Epirubicin hydrochloride is given at the bladder.
- Other types of cancer (so-called solid tumors) include:
  - brain, breast, lung, colon, kidney, gastrointestinal tract, and urinary tract cancers
  - Certain leukemias (types of blood cancer) and lymphomas (certain forms of cancer of the blood and lymphatic system)

- Concomitant administration of certain medicines for fighting cancer (so-called cytostatics) can increase the effect of Epirubicin hydrochloride 2 mg/ml.
- Epirubicin hydrochloride 2 mg/ml is taken orally and taken with or after a meal.

- This medicine is administered by medical personnel. It is not to be given at home.
- If you have any side effects, talk to your doctor or pharmacist.
- If you get side effects, talk to your doctor or pharmacist. This leaflet cannot provide all the information that you need to know about the possible effects of this medicine.
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- You are advised to take all the medicine of your course as you have been prescribed.

- When you empty your bladder the crystals may have come out of suspension. You may notice crystals in your urine, which is normal. You should continue to take the medicine even if you see these crystals.

- Do not use this medicine during pregnancy in women of childbearing age without previous consultation with your doctor.

- Epirubicin hydrochloride 2 mg/ml may also be used intravenously directly into the vein.
- Epirubicin hydrochloride 2 mg/ml in any way, including the preparation and administration, or use it after the expiry date.
- The solution must be used immediately. If you do not use it to eat, it may harm others, even if the symptoms are the same as yours.

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Each carton contains a single vial.

2.1 Epirubicin hydrochloride vial:

- **for injection**

Viaflo     Refrigerator    Room temperature

Store in the refrigerator (2-8°C).

2.2 Solvent for epirubicin hydrochloride dilution has to be 0.6-1.6 mg/ml.

- be administered intravenously. The concentration of the dilution has to be 0.6-1.6 mg/ml.

DILUTION TABLE FOR BLADDER ADMINISTRATION via the bladder (intravesical administration) (100-120 mg/m² of body surface area).

- other cancer medicines the dose is reduced. The dose is administered as a single dose or distributed over 2-3 days.

**POSSIBLE SIDE EFFECTS**

If two medicines are taken together, the negative effect on bone marrow disorders); when used together with epirubicin it may have a negative effect on bone marrow.

**Breast-feeding**

You should also prevent pregnancy if your partner is treated with epirubicin. Please consult your doctor if you are breast-feeding or a breast-feeding woman's partner is treated with epirubicin.

**Fertility, pregnancy and breast-feeding**

- the cancer has penetrated the bladder wall
- there is a high risk of cancer spreading to the lymph nodes (especially to the nodes around the groins)
- the cancer is in the lymph nodes around the groins and/or in the liver

- severe infections or bleedings
- depression
- disorders (peripheral neuropathy), headache

**Common Side-effects and Adverse Reactions**

The following side-effects can, amongst others, occur:

- infections or bleedings
- low blood count
- liver function disorder
- infections or bleedings
- headache

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**Drug interaction**

- the medicines mentioned in this section may be known to you under different names.

- to ensure the number of cells in your blood does not drop too low.

- to check the level of uric acid in your blood. Your doctor will check this.

- eye infections
- controller of the biliary tract
- bowel obstruction
- blood pressure
- potassium level in your blood
- any medicines that cause heart failure

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**HOW TO STORE EPIRubicin HYDROCHLORIDE 2 mg/ml**

Stor in the refrigerator (2°C-8°C). Store and transport refrigerated.

Do not freeze.

**Acute Graft-versus-host disease**

When you empty your bladder after the medicine has been given, the dose schedule is determined, whereby your length and your weight are taken into consideration by patients on a regular basis. A concentration of less than 5 mg/ml of epirubicin hydrochloride is given in the bladder (intravesical administration) (100-120 mg/m² of body surface area).

- other cancer medicines the dose is reduced. The dose is administered as a single dose or distributed over 2-3 days.

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