

PACKAGE LEAFLET

**TEPHARIX 100 mg powder for concentrate for solution for infusion
Intravenously.**

Sterile Cytotoxic

- **Active ingredient:** Each vial contains 100 mg Thiotepa. After reconstitution with 10 mL of water for injections, each mL contains 10 mg Thiotepa.
- **Excipients:** The product does not contain any excipients.

▼ This medicine is subject to additional monitoring. This triangle will allow for the rapid identification of new safety information. You can help by reporting any side effects that occur. See the end of Section 4 for information on how to report side effects.

Before use this medicine, please read this PATIENT INFORMATION LEAFLET carefully, as it contains important information for you.

- *Keep this leaflet. You may need to read it again later.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *When using this medicine, tell your doctor or hospital that you are using this medicine.*
- *Follow these instructions exactly. Do not use higher or lower doses than the dose recommended to you*

In this patient information leaflet:

1. ***What is TEPHARIX and what is it used for?***
2. ***Precautions before using of TEPHARIX***
3. ***How to use TEPHARIX?***
4. ***What are the possible side effects?***
5. ***How to store TEPHARIX?***

1. What is TEPHARIX and what it is used for?

TEPHARIX contains the active ingredient Thiotepa, which belongs to a group of drugs called alkylating agents. Each vial contains 100 mg Thiotepa as active ingredient. The product does not contain any excipients. After reconstitution with 10 mL of water for injection, each mL contains 10 mg (10 mg/mL) Thiotepa.

TEPHARIX is a lyophilized powder presented in a Type I glass vial. It is presented with 1 vial and patient information leaflet in each box.

TEPHARIX is used to prepare patients for bone marrow transplantation. It shows effect by tearing to pieces bone marrow cells. As a result of this effect, it enables the transplantation of new bone marrow cells (hematopoietic progenitor cells) that enable the body to produce healthy blood cells.

TEPHARIX can be used in adults, children and adolescents.

2. Precautions before using of

TEPHARIX Do not use TEPHARIX:

- If you are allergic to Thiotepa,
- If you are pregnant or think you may be pregnant
- If you are breast-feeding,
- When yellow fever vaccine, live virus and bacterial vaccines are administered.

Use TEPHARIX carefully for following conditions:

If you have the following conditions, talk to your doctor:

- Liver or kidney problems,
- Heart or lung problems,
- If you have an epileptic seizure/attack or have had a seizure/attack in the past (if treated with phenytoin or fosphenytoin)

Your doctor will regularly monitor your heart, liver and kidney functions during treatment.

Since TEPHARIX breaks down the bone marrow cells that are responsible for the production of blood cells, regular blood tests will be performed during treatment to check your blood cell counts. You will be given anti-infectives to prevent and manage infections.

TEPHARIX may cause another type of cancer in the future. Your doctor will talk to you about this risk.

Use with previous treatments (such as radiation) and other cancer drugs may increase the risk of lung damage, hepatic vein occlusion (such as hepatic veno-occlusive disease), or toxic reactions (such as encephalopathy).

Before getting vaccinated, tell your doctor. Simultaneous use with live vaccines is not recommended. Your doctor will guide you regarding the simultaneous use of TEPHARIX with other medications.

Your doctor will inform you about the possible effects of TEPHARIX on reproductive function.

The patient should be carefully observed during simultaneous use of TEPHARIX with CYP2B6 inhibitors (e.g. clopidogrel and ticlodipine, which reduce the risk of blood clot formation by preventing platelet aggregation) and CYP3A4 inhibitors (e.g. azole group antifungals used in fungal infections and macrolide group antibiotics such as erythromycin, clarithromycin and telithromycin used in bacterial infections and protease inhibitor group antibiotics) (see SmPC 4.4).

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using TEPHARIX with food and drink

No interactions with food or drink have been reported due to the method of application.

Pregnancy

Before use this medicine, consult your doctor or your pharmacist.

If you are pregnant or think you may be pregnant, you should consult your doctor before using TEPHARIX. You should not use TEPHARIX during pregnancy.

Male and female patients using TEPHARIX should use effective birth control methods during treatment.

TEPHARIX may impair male and female fertility. Male patients should investigate sperm preservation status before starting treatment and should not have children within one year after stopping the treatment.

You should not use TEPHARIX during pregnancy.

If you realise that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using the medicine.

If you are breast-feeding, you should tell your doctor before using TEPHARIX.

It is not known whether this medicinal product passes into breast milk. As a precaution, women should not breastfeed during treatment with TEPHARIX.

Driving and using machinery

Some adverse events of Thiotepe, such as dizziness, headache, and blurred vision, are likely to affect your ability to drive and operate machinery.

If you experience any of these effects, do not drive or operate machinery.

Important information about some of the excipients contained in TEPHARIX

It does not contain any excipients that require warning.

Use with other drugs

If you are taking any other medicine, have recently taken it or might take it, tell your doctor or pharmacist.

TEPHARIX may interact with other drugs. Using more than one drug at the same time is very important because it can strengthen or weaken the effects of the drugs.

• If you are using any of the following medicines, be sure to inform your doctor before taking TEPHARIX:

- Clopidogrel, Ticlodipine (an anticoagulant drug)
- Azole group antifungals (a group of drugs used against infections caused by fungi)
- Erythromycin, Clarithromycin, Telithromycin, Rifampicin (a group of drugs used against infections caused by bacteria)
- Carbamazepine, Phenobarbital, Phenytoin (a drug used to treat epilepsy)
- Ifosfamide, Cyclophosphamide (a drug used in cancer treatment)
- Tamoxifen (a drug used in breast cancer)
- Bupropion (an antidepressant medication)
- Efavirenz (an antiviral drug)

- Cyclosporine, Tacrolimus (a drug used to suppress the immune system)

- Products that may result in an increase in other hematological side effects, such as:
 - Cyclophosphamide, Melphalan, Busulfan, Fludarabine, Treosulfan (a drug used in cancer treatment)

- Before getting vaccinated, talk to your doctor. Live virus and bacterial vaccines such as the ones below should not be administered and at least 3 months should pass between the end of treatment and vaccination.

- Yellow fever vaccine

If you are currently using or have recently used any prescription or non-prescription medication, please inform your doctor or pharmacist about them.

3. How to use TEPHARIX

Instructions for proper use and dosage/frequency of administration:

Your doctor will determine the necessary dosage according to your body surface area or weight and your disease and administer it to you.

Your infusions will be given every 12 or 24 hours. Treatment may last up to 5 days. Frequency of administration and duration of treatment will vary depend on your disease.

Administration route and method:

TEPHARIX is administered by an experienced healthcare professional as an intravenous (intravenous/vein) infusion after dilution of each vial. Each infusion will take 2-4 hours.

Different age groups:

- **Use in children:**

Your doctor will determine the necessary dosage according to your body surface area or weight and your disease and administer it to you.

- **Use in the elderly:**

Clinical studies have not demonstrated the need for dosage adjustment.

Special use cases:**Kidney/liver failure:**

If you have kidney or liver problems, your doctor will consider the necessary dosage depending on the severity of your problems.

If you have the impression that the effect of TEPHARIX is too strong or too weak, talk to your doctor or pharmacist.

If you use more TEPHARIX than you should:

If you have used more TEPHARIX than you should, talk to a doctor or pharmacist.

If you forget to use TEPHARIX

Do not take a double dose to make up for a forgotten dose.

Possible effects when treatment with TEPHARIX is finalized

Do not stop using TEPHARIX without consulting your doctor.

4. What are the possible side effects?

Like all medicines, TEPHARIX may cause side effects in people who are sensitive to the ingredients it contains, but these side effects are not seen in everyone.

The most serious side effects of TEPHARIX treatment or transplant procedure may include the following.

If any of the following occur, stop using TEPHARIX and IMMEDIATELY notify your doctor or go to the emergency department of the nearest hospital:

- Decrease in the number of circulating blood cells (the intended effect of the medication to prepare you for the transplant (cell transplant) infusion)
- Infection
- Liver disorders including hepatic vein occlusion
- The graft (transplanted cell) may attack your body (graft versus host disease, GVHD)
- Respiratory problems

Your doctor will regularly monitor your blood counts and liver enzymes to detect and manage these conditions.

These are all very serious side effects.

If you have any of these, it means that you have a serious allergy to TEPHARIX. You may need urgent medical attention or hospitalization.

Very common	: It can be seen in at least one in 10 patients.
Common	: It may be seen in less than one in 10 patients, but more than one in 100 patients.
Uncommon	: It may occur in less than one in 100 patients, but in more than one in 1,000 patients..
Rare	: It may occur in less than one in 1,000 patients, but in more than one in 10,000 patients.
Very rare	: It may be seen in less than 1 in 10,000 patients.
Unknown	: It cannot be estimated based on the available data.

Side effects of TEPHARIX may occur at certain frequencies defined as follows:

Very common

- Increased susceptibility to infection
- Inflammation throughout the body (sepsis)

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Decreased white blood cell, platelet and red blood cell count (anemia)

- Transplanted cells attack your body (graft versus host disease)
- Dizziness, headache, blurred vision
- Uncontrollable shaking of the body (convulsion)
- Tingling, stinging or numb feeling (paresthesia)
- Partial loss of movement
- Cardiac arrest
- Nausea, vomiting, diarrhea
- Inflammation of the oral mucosa (mucositis)
- Throat, stomach, intestinal irritation
- Inflammation in the large intestine
- Loss of appetite, anorexia
- High glucose (blood sugar) level in the blood
- Skin rash, itching, peeling
- Skin discoloration (not to be confused with jaundice – see below)
- Skin redness (erythema)
- Hair loss
- Back and abdominal pain
- Muscle and joint pain
- Abnormal electrical activity in the heart (arrhythmia)
- Inflammation in lung tissue
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- Liver enlargement
- Changes in organ functions
- Occlusion of the hepatic vein (veno-occlusive liver disease, VOD) - Yellowing of the skin and eyes (jaundice)
- Hearing impairment
- Lymphatic obstruction (blockage in the lymph nodes)
- Hypertension
- Increase in liver, kidney and digestive enzymes
- Abnormal blood electrolytes (electrically charged minerals found in the blood as dissolved salts)
- Weight gain
- Fever, general weakness, chills
- Bleeding (hemorrhage)
- Nosebleeds
- General swelling (edema) due to fluid retention
- Pain or inflammation at the injection site
- Eye infection (conjunctivitis)
- Decrease in sperm cell count
- Vaginal bleeding
- Absence of menstrual periods (amenorrhea)
- Memory loss
- Delay in weight and height gain
- Bladder dysfunction
- Insufficient testosterone production
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- Insufficient thyroid hormone production
- Insufficient activity of the pituitary gland
- State of mental confusion

Common

- Anxiety disorder, confusion
- Abnormal bleeding outward from one of the arteries in the brain (intracranial aneurysm)
- Increase in creatinine level
- Allergic reactions
- Blockage in a blood vessel (embolism)
- Heart rhythm disorder
- Heart failure
- Cardiovascular failure
- Oxygen deficiency
- Fluid accumulation in the lungs (pulmonary edema, pulmonary edema)
- Bleeding in the lungs
- Respiratory arrest
- Blood in the urine (hematuria) and moderate renal failure
- Inflammation of the urinary bladder
- Discomfort during urination and decreased urine output (dysuria and oliguria)
- Increase in the amount of nitrogen compounds in the bloodstream (increase in BUN)
- Cataract
- Liver failure
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- Cerebral hemorrhage (brain hemorrhage)
- Cough
- Constipation and stomach discomfort
- Intestinal obstruction - Stomach perforation
- Changes in muscle tone
- Major lack of coordination in muscle movements
- Bruising due to decreased platelet count
- Menopause symptoms
- Cancer (second primary malignancies)
- Abnormal brain function
- Infertility in men and women

Uncommon

- Inflammation and flaking of the skin (erythrodermic psoriasis)
- Delirium (mental dysfunction), irritability, hallucinations (delusions), agitation (nervousness/anxiety)
- Digestive system ulcer
- Inflammation of the heart muscle tissue (myocarditis)
- Abnormal heart condition (cardiomyopathy)

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Unknown

- Increased blood pressure in the lung arteries (blood vessels) (pulmonary arterial hypertension)
- Serious skin damage that potentially covers the entire body surface and can be life-threatening (e.g. severe lesions, bullae, etc.)
- Damage to a certain part of the brain (the part called white matter), damage that can be life-threatening (leukoencephalopathy)

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

Reporting of side effects

If you experience any side effects, whether or not they are included in the User Manual, talk to your doctor, pharmacist or nurse. Also, report any side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Reporting" icon on the www.titck.gov.tr website or by calling the side effect reporting line at 0 800 314 00 08. By reporting any side effects that occur, you will contribute to obtaining more information about the safety of the medication you are using.

5. How to store TEPHARIX?

Keep TEPHARIX in its packaging and out of sight and reach of children.

Store in the refrigerator at 2°C-8°C. Do not freeze.

After reconstitution, the product is stable for 8 hours when stored at 2°C-8°C.

After dilution, the product is stable for 24 hours when stored at 2°C-8°C, and for 4 hours when stored at 25°C. From a microbiological point of view, the product should be used immediately after dilution.

Use in accordance with the expiration date.

Do not use TEPHARIX after the expiry date on the packaging..

The waste of inner packaging of cytotoxic and cytostatic human medical products that are emptied as a result of their use are HAZARDOUS WASTE and the management of these wastes is carried

out in accordance with the Waste Management Regulation published in the Official Gazette dated 2/4/2015 and numbered 29314.

Do not throw away expired or unused medicines! Give them to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

License holder:

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Bu kullanma talimatı ../../.... tarihinde onaylanmıştır.

THE FOLLOWING INFORMATION IS FOR HEALTH CARE PERSONNEL WHO WILL APPLY THIS MEDICINE.

1. SPECIAL WARNINGS FOR DISPOSAL AND OTHER PROCEDURES

General

Procedures for handling and disposal of anticancer drug products should be considered. All transfers require strict adherence to aseptic techniques, preferably with a vertical laminar flow safety hood.

As with other cytotoxic compounds, care should be taken to avoid accidental contact with skin and mucous membranes during handling and preparation of TEPHARIX. Topical reactions associated with accidental exposure to Thiotepa may occur. Indeed, it is recommended to wear gloves when preparing the infusion solution. If Thiotepa solution accidentally comes into contact with the skin, wash the skin immediately and thoroughly with plenty of water and soap. If Thiotepa accidentally comes into contact with mucous membranes, the mucous membranes should also be thoroughly washed with water.

TEPHARIX Dose Calculation

TEPHARIX is administered to patients in combination with other chemotherapeutic drug products at different doses before conventional hematopoietic progenitor cell transplantation (HPHN) for hematological diseases or solid tumors.

TEPHARIX dosing is reported according to the type of HPHN (autologous or allogeneic) and disease in adults and children.

Posology in Adults

OTHOLOG HPHN

Hematological diseases

The recommended dose ranges from 125 mg/m²/day (3.38 mg/kg/day) to 300 mg/m²/day (8.10 mg/kg/day) administered as a single daily infusion for 2 to 4 consecutive days, depending on the combination with other chemotherapy drug products prior to autologous HPHN, without exceeding a total maximum cumulative dose of 900 mg/ m² (24.32 mg/kg) during the entire conditioning regimen.

LYMPHOMA

In hematological diseases, the recommended dose ranges from 125 mg/m²/day (3.38 mg/kg/day) to 300 mg/m²/day (8.10 mg/kg/day) administered as a single daily infusion for 2 to 4 consecutive days, depending on the combination with other chemotherapy drug products prior to autologous HPHN, without exceeding a total maximum cumulative dose of 900 mg/ m² (24.32 mg/kg) during the entire conditioning regimen.

CENTRAL NERVOUS SYSTEM (CNS) LYMPHOMA

The recommended dose is 185 mg/m²/day (5 mg/kg/day) administered as a single daily infusion for 2 consecutive days prior to autologous HPHN without exceeding a total maximum cumulative dose of 370 mg/ m² (10 mg/kg) during the entire conditioning regimen.

MULTIPLE MYELOMA

The recommended dose ranges from 150 mg/m²/day (4.05 mg/kg/day) to 250 mg/ m²/day (6.76 mg/kg/day) administered as a single daily infusion for 3 consecutive days in combination with other chemotherapy drug products prior to autologous HPHN without exceeding a total maximum cumulative dose of 750 mg/ m² (20.27 mg/kg) during the entire conditioning regimen.

Solid tumors

In solid tumors, the recommended dose ranges from 120 mg/ m²/day (3.24 mg/kg/day) to 250 mg/ m²/day (6.76 mg/kg/day) administered as one or two daily infusions for 2 to 5 consecutive days, depending on the combination with other chemotherapy drug products prior to autologous HPHN, without exceeding a total maximum cumulative dose of 800 mg/ m² (21.62 mg/kg) during the entire conditioning regimen.

BREAST CANCER

The recommended dose ranges from 120 mg/m²/day (3.24 mg/kg/day) to 250 mg/m²/day (6.76 mg/kg/day) administered as a single daily infusion for 3 to 5 consecutive days, depending on the combination with other chemotherapy drug products prior to autologous HPHN, without exceeding a total maximum cumulative dose of 800 mg/m² (21.62 mg/kg) during the entire conditioning regimen.

CENTRAL NERVOUS SYSTEM TUMORS

The recommended dose ranges from 125 mg/m²/day (3.38 mg/kg/day) to 250 mg/ m²/day (6.76 mg/kg/day) administered as one or two divided infusions daily for 3 to 4 consecutive days, depending on the combination with other chemotherapy drug products prior to autologous HPHN, without exceeding a total maximum cumulative dose of 750 mg/ m² (20.27 mg/kg) during the entire conditioning regimen.

OVARIAN CANCER

The recommended dose is 250 mg/ m²/day (6.76 mg/kg/day) administered as a single daily infusion for 2 consecutive days prior to autologous HPHN without exceeding a total maximum cumulative dose of 500 mg/ m² (13.51 mg/kg) during the entire conditioning regimen.

GERM CELL TUMORS

The recommended dose ranges from 150 mg/ m²/day (4.05 mg/kg/day) to 250 mg/ m²/day (6.76 mg/kg/day) administered as a single daily infusion for 3 consecutive days, depending on the combination with other chemotherapy drug products prior to autologous HPHN, without exceeding a total maximum cumulative dose of 750 mg/ m² (20.27 mg/kg) during the entire conditioning regimen.

ALLOGENEIC HPHN

Hematological Diseases

In hematologic diseases, the recommended dose ranges from 185 mg/ m²/day (5 mg/kg/day) to 481 mg/ m²/day (13 mg/kg/day) administered as one or two divided infusions daily for 1 to 3 consecutive days, depending on the combination with other chemotherapy drug products prior to allogeneic HPHN, without exceeding a total maximum cumulative dose of 555 mg/m² (15 mg/kg) during the entire conditioning regimen.

LYMPHOMA

The recommended dose is 370 mg/m²/day (10 mg/kg/day) administered in two divided infusions prior to allogeneic HPHN, without exceeding a total maximum cumulative dose of 370 mg/ m² (10 mg/kg) throughout the conditioning regimen.

MULTIPLE MYELOMA

The recommended dose is 185 mg/ m²/day (5 mg/kg/day) administered as a single daily infusion prior to allogeneic HPHN without exceeding a total maximum cumulative dose of 185 mg/ m² (5 mg/kg) during the entire conditioning regimen.

LEUKEMIA

The recommended dose ranges from 185 mg/ m²/day (5 mg/kg/day) to 481 mg/ m²/day (13 mg/kg/day) administered as one or two divided infusions daily for 1 to 2 consecutive days, depending on the combination with other chemotherapy drug products prior to allogeneic HPHN,

without exceeding a total maximum cumulative dose of 555 mg/ m² (15 mg/kg) during the entire conditioning regimen.

THALASSEMIA

The recommended dose is 370 mg/ m²/day (10 mg/kg/day) administered in two divided daily infusions prior to allogeneic HPHN without exceeding a total maximum cumulative dose of 370 mg/m m² (10 mg/kg) during the entire conditioning regimen.

Pediyatrik popülasyon:

OTHOLOG *HPHN*

Solid tumors

In solid tumors, the recommended dose ranges from 150 mg/ m²/day (6 mg/kg/day) to 350 mg/ m²/day (14 mg/kg/day) administered as a single daily infusion for 2 to 3 consecutive days, depending on the combination with other chemotherapy drug products prior to autologous HPHN, without exceeding a total maximum cumulative dose of 1050 mg/ m² (42 mg/kg) during the entire conditioning regimen.

CENTRAL NERVOUS SYSTEM TUMORS

The recommended dose ranges from 250 mg/ m²/day (10 mg/kg/day) to 350 mg/ m²/day (14 mg/kg/day) administered as a single daily infusion for 3 consecutive days, depending on the combination with other chemotherapy drug products prior to autologous HPHN, without exceeding a total maximum cumulative dose of 1050 mg/ m² (42 mg/kg) during the entire conditioning regimen.

ALLOGENEIC HPHN

Hematological diseases

In hematologic diseases, the recommended dose ranges from 125 mg/ m²/day (5 mg/kg/day) to 250 mg/ m²/day (10 mg/kg/day) administered as one or two divided infusions daily for 1 to 3 consecutive days, depending on the combination with other chemotherapy drug products prior to allogeneic HPHN, without exceeding a total maximum cumulative dose of 375 mg/ m² (15 mg/kg) during the entire conditioning regimen.

LEUKEMIA

The recommended dose is 250 mg/ m²/day (10 mg/kg/day) administered in two divided infusions prior to allogeneic HPHN without exceeding a total maximum cumulative dose of 250 mg/ m² (10 mg/kg) during the entire conditioning regimen.

THALASSEMIA

The recommended dose ranges from 200 mg/ m²/day (8 mg/kg/day) to 250 mg/ m²/day (10 mg/kg/day) administered in two divided infusions prior to allogeneic HPHN without exceeding a total maximum cumulative dose of 250 mg/ m² (10 mg/kg) during the entire conditioning regimen.

REFRACTORY CYTOPENIA

The recommended dose is 125 mg/ m²/day (5 mg/kg/day) administered as a single daily infusion for 3 consecutive days prior to allogeneic HPHN without exceeding a total maximum cumulative dose of 375 mg/m² (15 mg/kg) during the entire conditioning regimen.

GENETIC DISEASES

The recommended dose is 125 mg/ m²/day (5 mg/kg/day) administered as a single daily infusion for 2 consecutive days prior to allogeneic HPHN without exceeding a total maximum cumulative dose of 250 mg/m² (10 mg/kg) during the entire conditioning regimen.

SICKLE CELL ANEMIA

The recommended dose is 250 mg/ m²/day (10 mg/kg/day) administered in two divided infusions prior to allogeneic HPHN without exceeding a total maximum cumulative dose of 250 mg/ m² (10 mg/kg) during the entire conditioning regimen.

Dilution

TEPHARIX should be reconstituted with 10 mL of sterile water for injection.

Using a syringe with a needle attached, aseptically draw 10 mL of sterile water for injection into the syringe.

Inject the contents of the syringe into the vial through the rubber stopper. Remove the syringe and needle and mix by hand by inverting several times.

Only colorless solutions containing no particulate matter should be used. Diluted solutions may sometimes show opacification; such solutions can still be administered.

Further Dilution in the Infusion Bag

The diluted solution is hypotonic and should be further diluted in 500 mL (1000 mL if the dose is greater than 500 mg) of 9 mg/mL (0.9%) sodium chloride solution for injection prior to administration or in an appropriate volume of 9 mg/mL (0.9%) sodium chloride to obtain a final TEPHARIX concentration between 0.5 and 1 mg/mL.

Administration

TEPHARIX infusion solution should be visually inspected for particulate matter prior to administration. Solutions containing precipitate should not be used.

The infusion solution should be administered to patients using an infusion set fitted with a 0.2 µm in-line filter. Filtration does not affect the potency of the solution.

TEPHARIX should be administered aseptically as a 2-4 hour infusion at room temperature (approximately 25°C) and under normal light conditions..

Before and after each infusion, the attached catheter line should be flushed with approximately 5 mL of 9 mg/mL (0.9%) sodium chloride for injection.

DESTRUCTION

TEPHARIX is for single use only. The waste of the inner packaging of cytotoxic and cytostatic human medical products that are emptied as a result of their use is HAZARDOUS WASTE and the management of these wastes is carried out in accordance with the Waste Management Regulation published in the Official Gazette dated 2/4/2015 and numbered 29314.