Package leaflet: Information for the patient

TEPADINA® 400 mg

powder and solvent for solution for infusion

thiotepa

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TEPADINA® is and what it is used for

TEPADINA® contains the active substance thiotepa, which belongs to a group of medicines called alkylating agents.

TEPADINA® is used to prepare patients for bone marrow transplantation. It works by destroying bone marrow cells. This enables the transplantation of new bone marrow cells (haematopoietic progenitor cells), which in turn enable the body to produce healthy blood cells.
TEPADINA® can be used in adults and children and adolescents.

2. What you need to know before you use TEPADINA®

Do not use TEPADINA®
- if you are allergic to thiotepa,
- if you are pregnant or think you may be pregnant,
- if you are breast-feeding,
- if you are receiving yellow fever vaccination, live virus and bacterial vaccines.

Warning and precautions
You should tell your doctor if you have:
- liver or kidney problems,
- heart or lung problems,
- seizures/fits (epilepsy) or have had them in the past (if treated with phenytoin or fosphenytoin).

Because TEPADINA® destroys bone marrow cells responsible for producing blood cells, regular blood tests will be taken during treatment to check your blood cell counts.
In order to prevent and manage infections, you will be given anti-infectives.

TEPADINA® may cause another type of cancer in the future. Your doctor will discuss this risk with you.

Other medicines and TEPADINA®
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility
You must tell your doctor if you are pregnant or you think you may be pregnant before you receive TEPADINA®. You must not use TEPADINA® during pregnancy.

Both women and men using TEPADINA® must use effective contraceptive methods during treatment.
After cessation of treatment women must use effective contraceptive methods for at least 6 months and men for at least 3 months.

It is not known whether this medicine is excreted in breast milk. As a precautionary measure, women must not breast-feed during treatment with TEPADINA®.

TEPADINA® can impair male and female fertility. Male patients should seek advice for sperm preservation before therapy is started.

Driving and using machines
It is likely that certain adverse reactions of thiotepa like dizziness, headache and blurred vision could affect your ability to drive and use machines. If you are affected, do not drive or use machines.

TEPADINA® contains sodium
This medicine contains 1 418 mg (61.6 mmol) sodium (main component of cooking/table salt) in each bag. This is equivalent to 70.9% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use TEPADINA®

Your doctor will calculate the dose according to your body surface or weight and your disease.

How TEPADINA® is given
TEPADINA® is administered by a qualified healthcare professional as an intravenous infusion (drip in a vein) after reconstitution of the individual bag. Each infusion will last 2-4 hours.

Frequency of administration
You will receive your infusions every 12 or 24 hours. The duration of treatment can last up to 5 days. Frequency of administration and duration of treatment depend on your disease.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most serious side effects of TEPADINA® therapy or the transplant procedure may include
- decrease in circulating blood cell counts (intended effect of the medicine to prepare you for your transplant infusion)
- infection
- liver disorders including blocking of a liver vein
- the graft attacks your body (graft versus host disease)
- respiratory complications

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

Side effects of TEPADINA® may occur with certain frequencies, which are defined as follows:

Very common side effects (may affect more than 1 in 10 people)
- increased susceptibility to infection
- whole-body inflammatory state (sepsis)
- decreased counts of white blood cells, platelets and red blood cells (anaemia)
- the transplanted cells attack your body (graft versus host disease)
- dizziness, headache, blurred vision
- uncontrolled shaking of the body (convulsion)
- sensation of tingling, pricking or numbness (paraesthesia)
- partial loss of movement
- cardiac arrest
- nausea, vomiting, diarrhoea
- inflammation of the mucosa of the mouth (mucositis)
- irritated stomach, gullet, intestine
- inflammation of the colon
- anorexia, decreased appetite
- high glucose in the blood
- skin rash, itching, shedding
- skin colour disorder (do not confuse with jaundice - see below)
- redness of the skin (erythema)
- hair loss
- back and abdominal pain, pain
- muscle and joint pain
- abnormal electrical activity in the heart (arrhythmia)
- inflammation of lung tissue
- enlarged liver
- altered organ function
- blocking of a liver vein (veno-occlusive disease, VOD)
- yellowing of the skin and eyes (jaundice)
- hearing impaired
- lymphatic obstruction
- high blood pressure
- increased liver, renal and digestive enzymes
- abnormal blood electrolytes
- weight gain
- fever, general weakness, chills
- bleeding (haemorrhage)
- nasal bleeding
- general swelling due to fluid retention (oedema)
- pain or inflammation at the injection site
- eye infection (conjunctivitis)
- decreased sperm cell count
- vaginal bleeding
- absence of menstrual periods (amenorrhea)
- memory loss
- delaying in weight and height increase
- bladder disfunction
- underproduction of testosterone
- insufficient production of thyroid hormone
- deficient activity of the pituitary gland
- confusional state

Common side effects (may affect up to 1 in 10 people)
- anxiety, confusion
- abnormal bulging outward of one of the arteries in the brain (intracranial aneurysm)
- creatinine elevated
- allergic reactions
- occlusion of a blood vessel (embolism)
- heart rhythm disorder
- heart inability
- cardiovascular inability
- oxygen deficiency
- fluid accumulation in the lungs (pulmonary oedema)
- pulmonary bleeding
- respiratory arrest
- blood in the urine (haematuria) and moderate renal insufficiency
- inflammation of the urinary bladder
- discomfort in urination and decrease in urine output (disuria and oliguria)
- increase in the amount of nitrogen components in the blood stream (BUN increase)

- cataract
- inability of the liver
- cerebral haemorrhage
- cough
- constipation and upset stomach
- obstruction of the bowel
- perforation of stomach
- changes in muscle tone
- gross lack of coordination of muscle movements
- bruises due to a low platelet count
- menopausal symptoms
- cancer (second primary malignancies)
- abnormal brain function
- male and female infertility

Uncommon side effects (may affect up to 1 in 100 people)
- inflammation and exfoliation of the skin (erythrodermic psoriasis)
- delirium, nervousness, hallucination, agitation
- gastrointestinal ulcer
- inflammation of the muscular tissue of the heart (myocarditis)
- abnormal heart condition (cardiomyopathy)

Not known (frequency cannot be estimated from the available data)
- increased blood pressure in the arteries (blood vessels) of the lungs (pulmonary arterial hypertension)
- severe skin damage (e.g. severe lesions, bullae, etc.) potentially involving the full body surface which can be even life-threatening
- damage to a component of the brain (the so called white matter) which can be even life-threatening (leukoencephalopathy).

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra. gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or AppleApp Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TEPADINA®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, label on aluminum wrapper and bag, after EXP. The expiry date refers to the last day of that month.

Store and transport refrigerated (2°C-8°C).
Do not freeze.
Keep the bag in the aluminum wrapper in order to protect from activation.

After the activation and reconstitution of the bag, the product is stable for up to 168 hours when stored at 2 °C - 8 °C and for up to 56 hours when stored at 25 °C. From a microbiological point of view, the product should be used immediately.

Any unused product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What TEPADINA® contains
- The active substance is thiotepa.

One bag contains 400 mg thiotepa.
After reconstitution with the solvent, each mL of solution contains 1 mg of thiotepa.

- The other ingredients are sodium chloride and water for injections (see section 2 “TEPADINA® contains sodium”).

What TEPADINA® looks like and contents of the pack
TEPADINA® is supplied in a dual chamber bag containing 400 mg thiotepa and 400 mL sodium chloride 9 mg/mL (0.9%) solution for injection.
After reconstitution, the bag contains a clear and colourless solution for infusion.

Each bag is packed in an aluminum wrapper.

Each carton contains 1 bag.

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