

TEPADINA- thiotepa injection, powder, for solution
ADIENNE SA

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

TEPADINA[®] 15 mg powder for concentrate for solution for infusion

Thiotepa

The following information is intended for medical or healthcare professionals only.

PREPARATION GUIDE

Read this guide prior to the preparation and administration of TEPADINA[®].

1. PRESENTATION

TEPADINA[®] is supplied as 15 mg powder for concentrate for solution for infusion.

TEPADINA[®] must be reconstituted and diluted prior to administration.

2. SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

General

Procedures for proper handling and disposal of anticancer medicinal products should be considered. All transfer procedures require strict adherence to aseptic techniques, preferably employing a vertical laminar flow safety hood.

As with other cytotoxic compounds, caution need to be exercised in handling and preparation of TEPADINA[®] solutions to avoid accidental contact with skin or mucous membranes. Topical reactions associated with accidental exposure to thiotepa may occur. In fact, the use of gloves is recommended in preparing the solution for infusion. If thiotepa solution accidentally contacts the skin, immediately the skin must be thoroughly washed with soap and water. If thiotepa accidentally contacts mucous membranes, they must be flushed thoroughly with water.

Calculation of dose of TEPADINA[®]

TEPADINA[®] is administered at different doses in combination with other chemotherapeutic medicinal products in patients prior to conventional haematopoietic progenitor cell transplantation (HPCT) for haematological diseases or solid tumours.

TEPADINA[®] posology is reported, in adult and paediatric patients, according to the type of HPCT (autologous or allogeneic) and disease.

Posology in adults

AUTOLOGOUS HPCT

Haematological diseases

The recommended dose in haematological diseases ranges from 125 mg/m²/day (3.38 mg/kg/day) to 300 mg/m²/day (8.10 mg/kg/day) as a single daily infusion, administered from 2 up to 4 consecutive days before autologous HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 900 mg/m² (24.32 mg/kg), during the time of the entire conditioning treatment.

LYMPHOMA

The recommended dose ranges from 125 mg/m²/day (3.38 mg/kg/day) to 300 mg/m²/day (8.10 mg/kg/day) as a single daily infusion, administered from 2 up to 4 consecutive days before autologous HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 900 mg/m² (24.32 mg/kg), during the time of the entire conditioning treatment.

CNS LYMPHOMA

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

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) as a single daily infusion, administered for 3 consecutive days before autologous HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 750 mg/m² (20.27 mg/kg), during the time of the entire conditioning treatment.

Solid tumours

The recommended dose in solid tumours ranges from 120 mg/m²/day (3.24 mg/kg/day) to 250 mg/m²/day (6.76 mg/kg/day) divided in one or two daily infusions, administered from 2 up to 5 consecutive days before autologous HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 800 mg/m² (21.62 mg/kg), during the time of the entire conditioning treatment.

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) as a single daily infusion, administered from 3 up to 5 consecutive days before autologous HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 800 mg/m² (21.62 mg/kg), during the time of the entire conditioning treatment.

CNS TUMOURS

The recommended dose ranges from 125 mg/m²/day (3.38 mg/kg/day) to 250 mg/m²/day (6.76 mg/kg/day) divided in one or two daily infusions, administered from 3 up to 4 consecutive days before autologous HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 750 mg/m² (20.27 mg/kg), during the time of the entire conditioning treatment.

OVARIAN CANCER

The recommended dose is 250 mg/m²/day (6.76 mg/kg/day) as a single daily infusion, administered in 2 consecutive days before autologous HPCT, without exceeding the total maximum cumulative dose of 500 mg/m² (13.51 mg/kg), during the time of the entire conditioning treatment.

GERM CELL TUMOURS

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

ALLOGENEIC HPCT

Haematological diseases

The recommended dose in haematological diseases ranges from 185 mg/m²/day (5 mg/kg/day) to 481 mg/m²/day (13 mg/kg/day) divided in one or two daily infusions, administered from 1 up to 3 consecutive days before allogeneic HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 555 mg/m² (15 mg/kg), during the time of the entire conditioning treatment.

LYMPHOMA

The recommended dose in lymphoma is 370 mg/m²/day (10 mg/kg/day) divided in two daily infusions before allogeneic HPCT, without exceeding the total maximum cumulative dose of 370 mg/m² (10 mg/kg), during the time of the entire conditioning treatment.

MULTIPLE MYELOMA

The recommended dose is 185 mg/m²/day (5 mg/kg/day) as a single daily infusion before allogeneic HPCT, without exceeding the total maximum cumulative dose of 185 mg/m² (5 mg/kg), during the time of the entire conditioning treatment.

LEUKEMIA

The recommended dose ranges from 185 mg/m²/day (5 mg/kg/day) to 481 mg/m²/day (13 mg/kg/day) divided in one or two daily infusions, administered from 1 up to 2 consecutive days before allogeneic HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 555 mg/m² (15 mg/kg), during the time of the entire conditioning treatment.

THALASSEMIA

The recommended dose is 370 mg/m²/day (10 mg/kg/day) divided in two daily infusions, administered before allogeneic HPCT, without exceeding the total maximum cumulative dose of 370 mg/m² (10 mg/kg), during the time of the entire conditioning treatment.

Posology in paediatric patients

AUTOLOGOUS HPCT

Solid tumours

The recommended dose in solid tumours ranges from 150 mg/m²/day (6 mg/kg/day) to 350 mg/m²/day (14 mg/kg/day) as a single daily infusion, administered from 2 up to 3 consecutive days before autologous HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 1050 mg/m² (42 mg/kg), during the time of the

entire conditioning treatment.

CNS TUMOURS

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

ALLOGENEIC HPCT

Haematological diseases

The recommended dose in haematological diseases ranges from 125 mg/m²/day (5 mg/kg/day) to 250 mg/m²/day (10 mg/kg/day) divided in one or two daily infusions, administered from 1 up to 3 consecutive days before allogeneic HPCT depending on the combination with other chemotherapeutic medicinal products, without exceeding the total maximum cumulative dose of 375 mg/m² (15 mg/kg), during the time of the entire conditioning treatment.

LEUKEMIA

The recommended dose is 250 mg/m²/day (10 mg/kg/day) divided in two daily infusions, administered before allogeneic HPCT, without exceeding the total maximum cumulative dose of 250 mg/m² (10 mg/kg), during the time of the entire conditioning treatment.

THALASSEMIA

The recommended dose ranges from 200 mg/m²/day (8 mg/kg/day) to 250 mg/m²/day (10 mg/kg/day) divided in two daily infusions, administered before allogeneic HPCT without exceeding the total maximum cumulative dose of 250 mg/m² (10 mg/kg), during the time of the entire conditioning treatment.

REFRACTORY CYTOPENIA

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

GENETIC DISEASES

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

SICKLE CELL ANAEMIA

The recommended dose is 250 mg/m²/day (10 mg/kg/day) divided in two daily infusions, administered before allogeneic HPCT, without exceeding the total maximum cumulative dose of 250 mg/m² (10 mg/kg), during the time of the entire conditioning treatment.

Reconstitution

TEPADINA[®] must be reconstituted with 1.5 ml of sterile water for injections.

Using a syringe fitted with a needle, aseptically withdraw 1.5 ml of sterile water for injections.

Inject the content of the syringe into the vial through the rubber stopper.
Remove the syringe and the needle and mix manually by repeated inversions.
Only clear colourless solutions, without any particulate matter, must be used.

Further dilution in the infusion bag

The reconstituted solution is hypotonic and must be further diluted prior to administration with 500 ml sodium chloride 9 mg/ml (0.9 %) solution for injection (1000 ml if the dose is higher than 500 mg) or with an appropriate volume of sodium chloride 9 mg/ml (0.9 %) in order to obtain a final TEPADINA[®] concentration between 0.5 and 1 mg/ml.

Administration

TEPADINA[®] infusion solution should be inspected visually for particulate matter and opalescence prior to administration. Solutions containing a precipitate should be discarded.

It is recommended that the infusion solution be administered to patients using an infusion set equipped with a 0.2 µm in-line filter.

TEPADINA[®] should be aseptically administered as a 2 - 4 hours infusion under room temperature and normal light conditions.

Prior to and following each infusion, the indwelling catheter line should be flushed with approximately 5 ml sodium chloride 9 mg/ml (0.9 %) solution for injection.

Disposal

TEPADINA[®] is for single use only.

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

PACKAGE LEAFLET: INFORMATION FOR THE USER

TEPADINA[®] 15 mg powder for concentrate for solution for infusion Thiotepa

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What TEPADINA[®] is and what it is used for
2. Before you use TEPADINA[®]
3. How to use TEPADINA[®]
4. Possible side effects
5. How to store TEPADINA[®]
6. Further information

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.

2. BEFORE YOU USE TEPADINA[®]

Do not use TEPADINA[®]

- if you are allergic (hypersensitive) to thiotepa,
- if you are pregnant or think you may be pregnant (see below),
- if you are breast-feeding,
- if you are receiving yellow fever vaccination, live virus and bacterial vaccines.

Take special care with TEPADINA[®]

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).

You will have to take regular blood tests during treatment to check your blood cell counts.

You will have to use anti-infectives to prevent and manage infections.

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

Pregnancy and breast-feeding

You must tell your doctor if you are or 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.

It is not known whether this medicinal product 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 for sperm preservation before therapy is started and should not father while treated and during the year after cessation of treatment.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 dilution of the individual vial. 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 3 days. Frequency of administration and duration of treatment depend on your disease.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TEPADINA[®] 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: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Very common side effects

- 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 (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

- 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

Uncommon side effects

- 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)
- male and female infertility

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or nurse.

5. HOW TO STORE TEPADINA®

Keep out of the reach and sight of children.

Do not use TEPADINA® after the expiry date which is stated on the carton and vial label, after EXP. The expiry date refers to the last day of that month.

Store and transport refrigerated (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.

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

6. FURTHER INFORMATION

What TEPADINA® contains

- The active substance is thiotepa. One vial contains 15 mg thiotepa. After reconstitution, each ml contains 10 mg thiotepa (10 mg/ml).
- TEPADINA® does not contain any other ingredients.

What TEPADINA® looks like and contents of the pack

TEPADINA® is a white crystalline powder supplied in a glass vial containing 15 mg thiotepa. Each carton contains 1 vial.

Marketing Authorisation Holder

ADIENNE S.r.l.
Via Broseta 64/B
24128 Bergamo
Italy

+39 035 19964047
adienne@adienne.com

Manufacturer

RIEMSER Arzneimittel AG
7 An der Wiek
17493 Greifswald
Insel Riems
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien

Eurocept International B.V.
Trapgans 5
NL-1244 RL, Ankeveen
Tél/Tel: +31-35 5283 957
info@eurocept.nl

Luxembourg/Luxemburg

Eurocept International B.V.
Trapgans 5
NL-1244 RL, Ankeveen
Tél/Tel: +31-35 5283 957
info@eurocept.nl

България

S&D Chemicals (Bulgaria) Ltd.
36, Dragan Tzankov blvd.
World Trade Center bl.B, офис 502
София BG 1057
Тел.: +359- (0) 2 971 21 30
info@sndchemicals.bg

Magyarország

Medical Maximum
Hegedus Gy. u. 93/D 8/3.
H-1133 Budapest
Tel.: + 36- (6) 302 510 086
sales@med-max.com

Česká republika

CSC Pharmaceuticals Handels GmbH
Gewerbegebiet Klein-Engersdorf
Gewerbestrasse 18-20
A-2102 Bisamberg
Tel: +43- (0) 2 262 606-0
office@csc-pharma.com

Malta

ADIENNE S.r.l.
Via Broseta 64/B
I-24128 Bergamo
Tel: +39-035 199 64047
adienne@adienne.com

Danmark

Eurocept International B.V.
Trapgans 5
NL-1244 RL, Ankeveen
Tlf: +31-35 5283 957
info@eurocept.nl

Nederland

Eurocept International B.V.
Trapgans 5
NL-1244 RL, Ankeveen
Tel: +31-(0)35 5283 957
info@eurocept.nl

Deutschland

RIEMSER Arzneimittel AG
An der Wiek 7
D - 17493 Greifswald - Insel Riems
Tel: +49- (0) 38 351 76-0
info@riemser.de

Norge

Eurocept International B.V.
Trapgans 5
NL-1244 RL, Ankeveen
Tlf: +31-35 5283 957
info@eurocept.nl

Eesti

RIEMSER Arzneimittel AG
An der Wiek 7

Österreich

Amomed Pharma
Nikolsdorfergasse 1/15

D - 17493 Greifswald - Insel Riems
Tel: +49-(0) 38 351 76-0
info@riemser.de

Ελλάδα

aVIPHARMA International S.A.
Μεσογείων 43
GR-151 26 Μαρούσι-Αθήνα
Τηλ: +30-210 6194 170
info@avipharma.gr

España

ADIENNE SPAIN S.L.
Passeig del Canal 5, Local 4
E-08980 Sant Feliu de Llobregat -
Barcelona
Tel: +34 93.666.25.61
adiennespain@adienne.com

France

RIEMSER Arzneimittel AG
An der Wiek 7
D - 17493 Greifswald - Insel Riems
Tél: +49 (0) 38 351 76-0
info@riemser.de

Ireland

ADIENNE S.r.l.
Via Broseta 64/B
I-24128 Bergamo
Tel: +39-035 199 64047
adienne@adienne.com

Ísland

Eurocept International B.V.
Trapgans 5
NL-1244 RL, Ankeveen
Sími: +31-35 5283 957
info@eurocept.nl

Italia

ADIENNE S.r.l.
Via Broseta 64/B
I-24128 Bergamo
Tel: +39-035 199 64047
adienne@adienne.com

Κύπρος

aVIPHARMA International S.A.

A- 1050 Wien
Tel: + 43- (0) 1 545 01 13 0
office@amomed.com

Polska

IMED POLAND Sp. z o.o.
314, Pulawska Str.
02-819 Warsaw
Tel: +48 - (0) 22 663 43 10
imed@imed.com.pl

Portugal

ADIENNE S.r.l.
Via Broseta 64/B
I-24128 Bergamo
Tel: +39-035 199 64047
adienne@adienne.com

România

Romfarmachim S.A. Foreign Trade
Co.
Intrarea Costache Negri no.11, Sector
5
Bucureşti 050554 - RO
Tel: + 40- (0) 21 3166284
romfarmachim@rdsmail.ro

Slovenija

Medis, d.o.o.
Brnčičeva 1
SI-1001 - Ljubljana
Tel: +386- (0) 1 561 21 19
info@medis.si

Slovenská republika

CSC Pharmaceuticals Handels GmbH
Gewerbegebiet Klein-Engersdorf
Gewerbestrasse 18-20
A-2102 Bisamberg
Tel: +43-(0)2 262 606-0
office@csc-pharma.com

Suomi/Finland

Eurocept International B.V.
Trapgans 5
NL-1244 RL, Ankeveen
Puh/Tel: +31-35 5283 957
info@eurocept.nl

Sverige

Eurocept International B.V.

Μεσογείων 43
GR-151 26 Μαρούσι-Αθήνα
Τηλ: +30-210 6194 170
info@avipharma.gr

Trapgans 5
NL-1244 RL, Ankeveen
Tel: +31-35 5283 957
info@eurocept.nl

Latvija
PEAN Ltd.
Duntes 12/22
Rīga LV 1005
Tel: + 371- 67392500
pean@mailbox.riga.lv

United Kingdom
ADIENNE S.r.l.
Via Broseta 64/B
I-24128 Bergamo
Tel: +39-035 199 64047
adienne@adienne.com

Lietuva
UAB Armila
Ateities 10
LT 08303 Vilnius
Tel: +370- (0) 5 2777596
info@armila.com

This leaflet was last approved in:

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>

PRINCIPAL DISPLAY PANEL - 15 mg Vial Carton

TEPADINA® 15 mg

Powder for concentrate for solution for infusion

Thiotepa
1 vial

Intravenous use, after reconstitution and dilution.

ADIENNE
PHARMA & BIOTECH

TEPADINA® 15 mg

Polvere per concentrato per soluzione per infusione
Powder for concentrate for solution for infusion
Polvo para concentrado para solución para perfusión

Tiotepa / Thiotepa

Leggere il foglio illustrativo prima dell'uso.
Tenere fuori dalla portata e dalla vista dei bambini.
Citotossico. Medicinale soggetto a prescrizione medica.

Read the package leaflet before use.
Keep out of the reach and sight of children.
Cytotoxic. Medicinal product subject to medical prescription.

Leer el prospecto antes de utilizar este medicamento.
Mantener fuera del alcance y de la vista de los niños.
Citotóxico. Medicamento sujeto a prescripción médica.

EU/1/10/622/001

ADIENNE
PHARMA & BIOTECH

TEPADINA® 15 mg

Polvere per concentrato per soluzione per infusione
Powder for concentrate for solution for infusion
Polvo para concentrado para solución para perfusión

Tiotepa / Thiotepa

1 flaconcino / 1 vial

Usò endovenoso, dopo la ricostituzione e la diluizione.

Intravenous use, after reconstitution and dilution.

Vía intravenosa, después de la reconstitución y dilución.

ADIENNE
PHARMA & BIOTECH

Polvo para concentrado para solución para perfusión
Powder for concentrate for solution for infusion

Tiotepa / Thiotepa

Un flaconcino contiene 15 mg di tiotepa.
Dopo la ricostituzione con 1,5 ml d'acqua per iniezione,
ogni ml di soluzione contiene 10 mg di tiotepa.

One vial contains 15 mg thiotepa.
After reconstitution with 1.5 ml of water for injection,
each ml contains 10 mg thiotepa.

Un vial contiene 15 mg de tiotepa.
Tras su reconstitución con 1,5 ml de agua para
preparaciones inyectables, cada mililitro de solución
contiene 10 mg de tiotepa.

TEPADINA® 15 mg

Conservare e trasportare in frigorifero (2°C-8°C).
Non congelare. Dopo la ricostituzione, usare entro 8 ore se conservato in frigorifero. Dopo la diluizione, usare entro 24 ore se conservato in frigorifero.

Store and transport refrigerated (2°C-8°C).
Do not freeze. After reconstitution, use within 8 hours when stored in a refrigerator. After dilution, use within 24 hours when stored in a refrigerator.

Almacenar y transportar refrigerado (2°C-8°C).
No congelar. Tras su reconstitución, utilizar en las 8 horas siguientes si se conserva en nevera. Tras su dilución, utilizar en las 24 horas siguientes si se conserva en nevera.

ADIENNE S.r.l., 24128 Bergamo (Italia/Italy)
 adienne@adienne.com



Il medicinale non utilizzato ed i rifiuti derivati da tale medicinale devono essere smaltiti in conformità alla normativa locale vigente.

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

La eliminación del medicamento no utilizado y de todos los materiales que hayan estado en contacto con él, se realizará de acuerdo con la normativa local.

ADN001

Lotto/Lot/Lote

SCAD./EXP/CAD

TEPADINA

thiotepa injection, powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53964-001
Route of Administration	INTRAVENOUS	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
THIOTEPA (UNII: 905Z5W3GKH) (THIOTEPA - UNII:905Z5W3GKH)	THIOTEPA	15 mg

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53964-001-01	1 in 1 BOX		
1		1 in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG FOR USE IN DRUG SHORTAGE		04/05/2011	

Labeler - ADIENNE SA (486304103)

Establishment

Name	Address	ID/FEI	Business Operations
IDT Australia Limited		753286384	API MANUFACTURE(53964-001)

Establishment

Name	Address	ID/FEI	Business Operations
THYMOORGAN PHARMAZIE GmbH		319029989	MANUFACTURE(53964-001) , ANALYSIS(53964-001)

Establishment

Name	Address	ID/FEI	Business Operations
LABOR L+S AG		313710642	ANALYSIS(53964-001)

Establishment

Name	Address	ID/FEI	Business Operations
BioChem GmbH		318354230	ANALYSIS(53964-001)