

Consumer Medicine Information

This leaflet provides important information about using TEPADINA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TEPADINA.**

Where to find information in this leaflet:

1. **Why am I using TEPADINA?**
2. **What should I know before I use TEPADINA?**
3. **What if I am taking other medicines?**
4. **How do I use TEPADINA?**
5. **What should I know while using TEPADINA?**
6. **Are there any side effects?**
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1. Why am I using TEPADINA?

TEPADINA contains the active ingredient THIOTEPA.

TEPADINA 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 should I know before I use TEPADINA?**Warnings**

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.

Check with your doctor if you have:

- liver or kidney problems,
- heart or lung problems
- seizures/fits (epilepsy) or have had them in the past.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

TEPADINA may increase the risk of having another cancer in the future. You will have regular follow up with your doctor after treatment with TEPADINA is completed.

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 medicines to treat infection.

Pregnancy and breastfeeding

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.

Men should not father a child while treated with TEPADINA and during the year after cessation of 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 advice for sperm preservation before therapy is started.