

**Thrombomax®**  
**Recombinant Human Interleukin 11**  
**12 MIU/1.5mg**

**1. What Thrombomax is and what is it used for?**

It is a platelet growth factor, which is produced by recombinant DNA technology. It promotes platelet production, by directly stimulating the proliferation of blood stem cells. The platelets produced in response to rh-IL-11 are structurally and functionally normal and possess a normal life span.

**It is used for the following indications:**

- Grade III or IV thrombocytopenia resulting from chemotherapy of solid tumors and/or non-myeloid leukemia.
- Reducing the need for platelet transfusion following myelosuppressive chemotherapy.
- It can be used in:
  - Aplastic anemia.
  - Myelodysplastic syndrome
  - Interferon induced thrombocytopenia.

**2. Before Thrombomax 1.5mg is administered to you:**

**Thrombomax 1.5mg should not be used:**

- If you are known or suspected to be hypersensitive (allergic) to IL-11 or any component of the product.

**Special care should be taken with Thrombomax 1.5mg:**

- Rh-11 should be used after chemotherapy, not recommended using before or in the course of chemotherapy.
- Platelet counts should be examined regularly. Stop using when the platelet reaches its normal limits.

- Watchful administration to patients with organic heart disease, especially patients with congestive heart failure, atrial fibrillation/flutter.
- Cautiously monitor the capillary vascular leakage syndrome, including weight, puffiness and serous cavity fluid etc.

**Pregnancy and Breast Feeding:**

*Pregnancy*

No sufficient data and strictly controlled information of clinical study in pregnant women exists. Therefore, it should only be administered to pregnant women when the potential benefit of the drug is more than the potential damage to the embryo/fetus

*Breast-Feeding*

Considering that many drugs can be excreted through breast milk and rh-IL-11 may result in adverse effects on the infant through milk, whether stop lactation or use the drug is up to the benefit to the mother.

**3. How Thrombomax 1.5mg is administered to you?**

**Method and routes of administration**

- Dissolve 1 vial rh-IL-11 with 1ml sterilized water for injection.
- Subcutaneous administration of rh-IL-11, 24-48 hours right after the course of chemotherapy is over or when the number of platelets is lower than normal.
- The course of rh-IL-11 treatment is generally 14-21 days.

**Dosage:**

- The recommended dose of Thrombomax in adults is 25-50 µg/kg given once daily.

**Thrombomax post administration effects:**

- After the number of platelets reaches normal level, stop using it.
- Treatment with Thrombomax should be discontinued at least two days before starting the next planned cycle of chemotherapy observed during the initial days of therapy, but these will dissipate with continued therapy.

#### 4. Possible Side Effects

The clinical studies showed that most of the side effects of rh-IL-11 were slight or moderate & relieved soon after cessation of therapy.

- Body: Edema, headache, fever & neutropenic fever.
- Cardiovascular system: Increased heart rate, vasodilation and irregular heart rhythm.
- Gastrointestinal system: Nausea, vomiting & fungal infections.
- Nervous system: Dizziness & insomnia.
- Respiratory system: shortness of breath, Flu-like symptoms, cough, pharyngitis, pleural effusion.
- Others: Rash, conjunctival congestion & transient blurred vision.

The incidence rates of some other side effects, such as paresthesia, dehydration, discoloration of skin, exfoliative dermatitis and hemorrhage from eye were also higher in some cases.

*Overdose:* Overdose of Thrombomax can result in adverse effects such as water sodium retention and atrial fibrillation. Reduce the dose or stop and closely monitor the patient.

*Drug Interaction:* no any adverse effect was found when using rh-IL-11 together with GCSF. Other drug interactions have not been fully studied.

#### 5. Storing Thrombomax 1.5mg

Store between 2 – 8 deg C.

#### 6. Further information

Rh-IL-11 (Thrombomax) 12MIU/1.5mg sterile lyophilized powder for injection in box of 1.

##### **Manufactured by:**

Beijing SL Pharmaceutical Co. Ltd.  
China

##### **Imported & marketed by:**

