

# Thrombexx<sup>®</sup>

(Hansenula derived recombinant Hirudin - RB variant)

## COMPOSITION :

Each ampoule(1ml) contains :  
Recombinant Hirudin 15 mg.

## THERAPEUTIC PROPERTIES :

Recombinant hirudin is a direct inhibitor of thrombin. It binds in a 1:1 ratio with thrombin thus blocking the coagulation cascade and the formation of thrombi.

Unlike heparins, the action of hirudin is totally independent from any coagulation cofactor that may interfere or alter its action.

## INDICATIONS :

Thrombexx is indicated in :

- \* Prophylaxis of deep-vein thrombosis in medical, surgical and orthopedic patients.
- \* At risk patients with ischemic heart disease and following the initial treatment of acute coronary syndromes
- \* Following the initiation of treatment of Heparin Induced Thrombocytopenia (HIT).

## DOSAGE AND ADMINISTRATION :

### Thrombo-prophylaxis in orthopedic, surgical and medical patients :

Thrombexx is useful in the prevention of thromboembolic complications in at risk patients. Thrombexx (15 mg) is administered by subcutaneous injection 5 - 15 minutes before orthopedic or general surgery (after induction of regional block anesthesia) then 15 mg twice daily for 9 - 12 days and in bedridden patients until patient is fully ambulant (maximum 12 days).

### Patients with Ischemic Heart Disease and following interventions for acute coronary syndromes and in critically ill cardiac patients:

Thromboprophylaxis using 15 mg administered by subcutaneous injection twice daily.

## PREGNANCY AND LACTATION :

The drug is contraindicated during pregnancy and lactation.

## SIDE EFFECTS :

\* Bleeding manifestations .

\* Hypersensitivity reaction including rash and urticaria, injection site reactions, very rarely anti-hirudin antibodies were detected on re-exposure.

## CONTRAINDICATIONS :

It should not be given in the following cases :

- \* Renal failure.
- \* Hepatic failure.
- \* Recent or active bleeding (biopsy of large vessels, intracranial or intraocular bleeding, hemorrhagic diathesis, active GIT bleeding, concomitant use of oral anticoagulant).
- \* Congenital coagulation disorders.
- \* Severe uncontrolled hypertension.
- \* Bacterial endocarditis.

## PRECAUTIONS :

Thrombexx should not be administered intramuscularly due to increased risk of haematoma formation. In patients with reduced creatinine clearance or with moderate hepatic insufficiency, monitoring with KCT (Kaolin clotting time) or PTT is mandatory.

## INTERACTIONS AND WARNING :

The drug should be used with caution in patients under other anticoagulants, anti-platelet agents and those using non-steroidal anti-inflammatory drugs.

## OVERDOSE :

It is difficult to neutralize the action of hirudin, the coagulation parameters could be partly corrected with the administration of desmopressin (DDVAP) by the intravenous route.

## PACKAGE & STORAGE :

- It is supplied in boxes of 3 ampoules, (1 ml) each.
- Storage at a temperature of (2 - 8 °C).

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