

VESSEL DUE F

Sulodexide

TRADE NAME OF THE MEDICINAL PRODUCT

VESSEL DUE F

COMPOSITION

250 LSU soft capsules

Each capsule contains: **Active ingredient:** Sulodexide 250 LSU. **Excipients:** sodium lauryl sarcosinate, silicon dioxide, triacetin, gelatin, glycerol, sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217), titanium dioxide (E171), red iron oxide (E172).

600 LSU/2 ml i.m./i.v. ampoules

Each ampoule contains: **Active ingredient:** Sulodexide 600 LSU. **Excipients:** sodium chloride, water for injectable preparations.

PHARMACEUTICAL FORMS AND PACKAGINGS

250 LSU soft capsules - box of 50 capsules.

600 LSU/2 ml i.m./i.v. injectable solution - box of 10 ampoules.

PHARMACOTHERAPEUTIC CLASS AND ACTIVITY

Antithrombotics/heparinoids.

VESSEL DUE F contains Sulodexide, a glycosaminoglycan with a strong antithrombotic effect on both arteries and veins.

Several clinical studies carried out by administering the product orally and by injection show that its antithrombotic activity is due to dose-dependent inhibition of some coagulative factors, above all activated X factor; as interference with thrombin remains at an insignificant level, the consequences of anticoagulative action are generally avoided. Antithrombotic action is also sustained by the inhibition of platelet aggregation and the activation of the circulating and parietal fibrinolytic system.

Sulodexide also brings back to normal the viscosimetric parameters that are usually altered in patients with vascular pathologies with thrombotic risk, mainly by reducing fibrinogen levels.

A normalising effect on modified lipidic levels by activation of lipoproteinlipase completes Sulodexide's pharmacological profile.

NAME AND ADDRESS OF THE MANUFACTURERS

Capsules

Soft capsules production: CATALENT ITALY S.p.A. - Aprilia (Latina) - Italy.

Packaging and control: ALFA WASSERMANN S.p.A. - Alanno (Pescara) - Italy.

Ampoules

ALFA WASSERMANN S.p.A. - Alanno (Pescara) - Italy.

THERAPEUTIC INDICATIONS

Vascular pathologies with thrombotic risk.

CONTRA-INDICATIONS

Individual hypersensitivity towards the product, towards heparin and heparin-like products. Diathesis and haemorrhagic diseases.

PRECAUTIONS FOR USE

In all cases where anticoagulant treatment is under way, haemocoagulative parameters should be monitored periodically.

As a precaution, the administration of VESSEL DUE F is not recommended during pregnancy.

INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

Sulodexide is a heparin-like molecule and may therefore increase the anticoagulative effects of heparin itself and of oral anticoagulants, if administered simultaneously.

As Sulodexide is an acid polysaccharide, if administered in extemporaneous association it may react by forming complexes with the base substances. The incompatible substances commonly used for extemporaneous association for phlebotomy are: vitamin K, B-complex vitamins, hydrocortisone, hyaluronidase, calcium gluconate, quaternary ammonium salts, chloramphenicol, tetracyclines and streptomycin.

SPECIAL WARNINGS

Keep out of the reach of children.

POSODOLOGY AND METHOD OF ADMINISTRATION

Soft capsules: 1 capsule, twice daily; not to be taken with meals.

Ampoules: 1 ampoule daily, i.m. or i.v.

Generally, it is advisable to start the therapy with ampoules and, after 15-20 days, continue with capsules for 30-40 days. The complete therapeutic cycle should be repeated at least twice per year. The quantity and frequency of doses may be modified at the physician's discretion.

UNDESIRABLE EFFECTS

Occasionally occurring:

Soft capsules: gastroenteric disorders with nausea, vomiting and epigastralgias.

Ampoules: pain, burning sensation and haematoma at the site of the injection.

Rare cases of sensitization may also occur with cutaneous phenomena or in other sites.

Any different or more serious undesirable effect should be reported immediately to your physician.

Attention: do not use the product after the expiry date indicated on the package.

ALFA WASSERMANN