

**ESSENTIAL INFORMATION (EI/CORE/ENGLISH)**

**Beriplast<sup>®</sup> P Combi-Set**

Based on the Company Core Package Insert (CCPI), Rev.: **22-JUL-2008**

## Essential information

It may be that the situation as given in the prescribing information specific for your country is different with regard to indications, contraindications, license holder etc. Please contact our local representative for further information.

### 1. Name

Beriplast® P Combi-Set

### 2. Composition

*Combi-Set I per 1 ml:*

Vial 1

Active ingredients: 90 mg fibrinogen (human plasma protein fraction), 60 U coagulation factor XIII (human plasma protein fraction). 1 Unit (U) corresponds to the Factor XIII activity of 1 ml fresh citrated plasma (pooled plasma of healthy donors).

Other ingredients: human albumin, L-arginine hydrochloride, L-isoleucine, sodium chloride, sodium citrate dihydrate, sodium L-glutamate monohydrate

Vial 2

Active ingredients: 1000 KIU (= Kallikrein Inactivator Unit), bovine lung aprotinin corresponding to 0.56 PEU [= Ph. Eur. Unit (1 PEU  $\triangleq$  1800 KIU)]

Other ingredients: sodium chloride, water for injections

*Combi-Set II per 1 ml*

Vial 3

Active ingredients: 500 IU human plasma protein fraction thrombin activity

Other ingredients: sodium chloride, sodium citrate-dihydrate

Vial 4

Active ingredients: 5.9 mg calcium chloride dihydrate

Other ingredients: water for injections

### 3. Indications

Beriplast P can be used locally as supportive treatment where standard surgical techniques are insufficient for improvement of haemostasis (including endoscopic treatment of bleeding gastroduodenal ulcer) and as a tissue glue to promote adhesion/sealing or as suture support.

### 4. Contraindications

Beriplast P must not be applied intravascularly.

Arterial and strong venous bleeding.

Known hypersensitivity to bovine proteins or to any other components of the product.

## 5. Special warnings and special precautions for use

Beriplast P may only be used for epilesional administration. Beriplast P must not be applied intravascularly! Life threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly.

As with any protein product, allergic type hypersensitivity reactions are possible. Signs of hypersensitivity reactions include hives, generalised urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis.

If allergic or anaphylactic reactions occur, the administration of Beriplast P has to be discontinued immediately and an appropriate treatment has to be initiated. Therapeutic measures depend on the nature and severity of the side effect.

Care is to be taken that parts of the body outside the desired application area are sufficiently protected (covered) to prevent tissue adhesion at undesired sites.

### *Special note on local injection:*

Administration of Beriplast P in the endoscopic treatment of gastrointestinal bleedings can cause tissue damage, which can lead to formation of intramural haematoma. Abdominal pain, nausea, or vomiting within 1 to 3 days after such endoscopic treatment can constitute symptoms of intramural haematoma. In patients with intramural haematoma of the duodenal wall, pancreatitis has been reported in single literature cases. Therefore, differential diagnosis for pancreatitis should be carefully evaluated.

### *Pregnancy and lactation*

Only limited experience regarding the administration of Beriplast P in pregnant women is available. Therefore, the product should be administered to pregnant or lactating women only if clearly indicated.

### *Virus safety*

Multiple measures to prevent infections are taken however, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV. The measures taken may be of limited value against non-enveloped viruses such as HAV and parvovirus B19.

Parvovirus B19 infection may be serious for pregnant women (fetal infection) and for individuals with immunodeficiency or increased red cell production (e.g. haemolytic anaemia).

## 6. Interactions with other medicinal products and other forms of interactions

Similar to comparable products or thrombin solutions, Beriplast P may be denatured after exposure with solutions containing alcohol, iodine or heavy metals (e.g., antiseptic solutions). Such substances should be removed to the greatest possible extent before applying Beriplast P.

## **7. Undesirable effects**

In very rare cases, hypersensitivity or allergic reactions (e.g., dyspnoea, flush/rash, urticaria, hypotension, bronchospasm) may occur, extending in isolated cases as far as anaphylactic shock. Such reactions may especially be seen, if the preparation is applied repeatedly, or administered to patients known to be hypersensitive to bovine proteins or other constituents of the product.

## **8. Prescription status**

Prescription-only drug.

## **9. Manufacturer**

CSL Behring GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

## **10. Date of information**

July 2008