F E I B A I M M U N O

Factor VIII Inhibitor Bypassing Fraction Human

Composition and Action

FEIBA IMMUNO is manufactured from plasma of HB_s Ag negative donors whose GPT levels are continually tested. When added in vitro to plasma containing Factor VIII inhibitor, **FEIBA IMMUNO** shortens activated partial thromboplastin time (PTT). The activity of **FEIBA IMMUNO** is expressed in FEIBA units and can be assayed by determining the shortening of activated PTT using a high titre Factor VIII inhibitor plasma (see also: Fraction FEIBA by Dr. F. Elsinger, presented during the 5th congress of the International Society on Thrombosis, Paris 1975). **FEIBA IMMUNO** is tested for safety and sterility as well as for the absence of HB_s Ag (by RIA) and pyrogens. The thrombin content of the preparation is negligible.

Indications

FEIBA IMMUNO can be administered alone or in combination with Factor VIII. It is mainly indicated to prevent or control haemorrhages in patients with a Factor VIII inhibitor.

---

* **FEIBA = Factor Eight Inhibitor Bypassing Activity**

** **1 FEIBA unit is defined as the FEIB-activity shortening the activated PTT of a high titre Factor VIII Inhibitor Reference plasma (IMMUNO House Standard) to 50 per cent of the blank value**

./. 2

TELEGRAMME IMMUNO WIEN
TELEX 47 4855 IMMUNO WIEN
TELEPHON (0222) 23 15 21
23 12 77 23 12 88
CREDITANSTALT BANKVEREIN KTO. 23 70007
OESTERR. POSTSPARKASSE KTO. 63 991

SHPL0000086_055_0001

Administration

Dissolve the contents of the vial in the enclosed solvent. **FEIBA IMMUNO will then be injected** intravenously: A maximum infusion rate of 1 U/kg per minute is recommended.

Dosage regimen

Present clinical evidence of the treatment of Factor VIII inhibitor patients suggests that the efficacy varies from patient to patient. Apart from Factors as yet unknown, this may have to do with the level of the inhibitor titre, i.e. high inhibitor titres require higher effective doses than the comparatively low inhibitor titres.

Determination of the whole blood clotting time (WBCT), according to "Lee White" and/or of the R-value of the thrombelastogram (TEG) will help to assess the adequate effective dose in each case and to check on therapeutic progress.

To give at least rough guidelines for dosage it is necessary to first differentiate between patients with high and those with low inhibitor titres.

I. Low inhibitor titres

A. An initial dose of 15 FEIBA units/kg is recommended. Additional dosage will depend on patient response as evidenced by the WBCT and/or the TEG.

1) Normalisation of WBCT and/or TEG

Administration need not be repeated.

./. 3

2) Moderate effect on WBCT and/or TEG

The initial dose should be increased by a further 15 units of **FEIBA IMMUNO** per Kg.

3) No change in WBCT and/or TEG

The initial dose should be increased by a further 3o units of **FEIBA IMMUNO** per Kg.

B. Maintenance Dose

More experience will be necessary before a general dosage regimen can be recommended. Preferably the maintenance dose should be calculated in correlation with the results obtained for WBCT and/or the TEG so that roughly normal values will be achieved.
The WBCT should be repeated according to the clinical condition of the patient and maintenance intervals may vary between 6 hours and 12 hours. The minimum maintenance dose should be 15 U/Kg of bodyweight.

II. High Inhibitor Titres

A. An initial dose of 3o FEIBA units per Kg is recommended. Additional dosage will depend on patient response as evidenced by WBCT and/or TEG.

1) Normalisation of WBCT and/or TEG

Dose need not be repeated.

2) Moderate effect on WBCT and/or TEG

The initial dose should be increased by a further 3o units of **FEIBA IMMUNO** per Kg.

3) No change in WBCT and/or TEG

The initial dose should be increased by a further 6o units of **FEIBA IMMUNO** per Kg.

./. 4

B. Maintenance Dose

More experience will be necessary before a general dosage regimen can be recommended. Preferably the maintenance dose should be calculated in correlation with the results obtained for WBCT and/or TEG so that about normal values will be achieved.
The WBCT should be repeated according to the clinical condition of the patient and maintenance intervals may vary between 6 hours and 12 hours. The minimum maintenance dose should be 15 U/Kg of bodyweight.
The effect on WBCT and the TEG of a single administration of **FEIBA IMMUNO** will last for 12 to 24 hours. Other parameters, in particular activated PTT, appear to be little influenced by **FEIBA IMMUNO.**

Caution

Although there has been no definite evidence of DIC attributable to the administration of **FEIBA IMMUNO,** it cannot be ruled out that DIC may be induced in certain cases. For this reason it is imperative that patients receiving **FEIBA IMMUNO** are continually examined for signs of accelerated coagulation. If an incipient DIC is suspected a platelet count and an assay of fibrinogen degradation products (FDP) should be carried out.

Treatment with **FEIBA IMMUNO** normalises WBCT although shortening of PTT may not take place. Thus, only WBCT - but not PTT - can be used to check on therapeutic progress.

Shelf-life and Storage

18 months when stored between +2 and +8 degrees C (Refrigerator).

./. 5

PACKS

FEIBA IMMUNO 100 equivalent to 100 FEIBA-units
- R/C bottle containing lyophilised FEIBA IMMUNO
- R/C bottle containing 10 ml Water for Injections B.P.
- Kit for reconstitution and injection

FEIBA IMMUNO 250 equivalent to 250 FEIBA-units
- R/C bottle containing lyophilised FEIBA IMMUNO
- R/C bottle containing 20 ml Water for Injections B.P.
- Kit for reconstitution and injection

FEIBA IMMUNO 500 equivalent to 500 FEIBA-units
- R/C bottle containing lyophilised FEIBA IMMUNO
- R/C bottle containing 20 ml Water for Injections B.P.
- Kit for reconstitution and injection

FEIBA IMMUNO 1000 equivalent to 1000 FEIBA-units
- R/C bottle containing lyophilised FEIBA IMMUNO
- R/C bottle containing 20 ml Water for Injections B.P.
- Kit for reconstitution and injection

Distributed by
IMMUNO LTD
Arctic House, Rye Lane, Dunton Green,
Nr. Sevenoaks, Kent TN14 5HB
Tel. Sevenoaks (0732) 50342

Manufactured by
ÖSTERREICHISCHES INSTITUT FÜR
HAEMODERIVATE GES.M.B.H.
Production Division of
IMMUNO AG Vienna Austria

GRO-C
GRO-C
1977 -01
SHPL0000086_055_0005