

Hamilton Regional Laboratory Medicine Program - HRLMP (effective at Hamilton Health Sciences, St. Joseph's Hospital and Associated Health Care Facilities)		
Initial Issue Date: Revision Date:	Administration Guidelines	Section: Laboratory Medicine Sub-Section: <i>Transfusion Medicine</i>
Title: FIBRINOGEN (Factor I)		Document Number:
<i>Approved By:</i> <i>Director, Laboratory Medicine</i> <i>Chair, Regional Transfusion Medicine Committee</i> <i>Head, Transfusion Medicine, HRLMP</i> <i>Manager, Transfusion Medicine, HRLMP</i> <i>Technical Specialist, Transfusion Medicine, HRLMP</i> <i>Chief of Nursing Practice, Hamilton Health Sciences</i> <i>Chief of Nursing Practice, St Joseph's Healthcare</i>		Page 1 of 3

Purpose: To Establish the Indications and Administration of Fibrinogen Concentrate

Scope: All patient care areas across HHS and St. Joseph's Healthcare

Definitions: Fibrinogen Concentrate is a human vapor-heated, sterile, freeze-dried fibrinogen concentrate made from pooled human plasma.

Other Names: FIBRINOGEN CONCENTRATE (Human)	Date Approved:	Pages: 1 of 3
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INDICATIONS:

- Investigational drug for treatment and prophylaxis of hemorrhage in patients with severe fibrinogen deficiency caused by:
 - Disseminated intravascular coagulation (DIC) and secondary hyperfibrinolysis
 - Hypofibrinogenemia triggered by acute intravascular consumption may also be related to incompatible transfusions, septicemia, massive trauma or major surgery, severe liver disease and malignant disease
 - Primary hyperfibrinolysis
 - Congenital hypo and afibrinogenemia
 - Congenital dysfibrinogenemia in patients with a hemorrhagic diathesis

DOSAGE:

- Depends primarily on the patient's fibrinogen content
- Fibrinogen concentration should be increased to at least 1 g/L; this level should be maintained until complete wound healing, (in hypofibrinogenemic patients with massive bleeding or who have undergone surgery or suffered major trauma)
- Initial dose to raise fibrinogen concentration to 1g/L in normal weight adults is suggested to be 3000 to 4000mg (3 to 4 g)
- Calculation of maintenance doses must rely on individual laboratory values
- Congenital deficiency patients, usually one third of the initial dose will be required for maintenance therapy
- Acquired deficiency patients, no guidelines for maintenance dosage can be provided; dosage can be derived from repeated fibrinogen assays
- Hypofibrinogenemia patients with lesser hemorrhagic risk or minor bleeding may be managed by single dose in adults of 1000 mg (1 g) or in children of 500 mg (0.5 g)

SUPPLIED:

- **Special Access Product - must obtain Emergency Drug Release - contact Transfusion Medicine**
- Supplied in single dose vials of 1000 mg human clottable fibrinogen
- Sterile freeze-dried product prepared from pooled human plasma
- Do not use past expiry date

RECONSTITUTION AND STABILITY:

- Preparation (including reconstituting, filtering, and pooling if required) is performed in Transfusion Medicine
- See manufacturer's information (package insert) for further information
- Reconstituted product should be used immediately

ADMINISTRATION:

- Product should not be further diluted

METHOD	WHO/WHERE	DILUTION	HOW TO ADMINISTER	INFUSION PUMP	PRECAUTIONS AND MONITORING
IV PUSH	N/A	N/A	N/A	N/A	N/A
MINIBAG/ BURETROL	RN	No	- Administer filtered product slowly 3 mL/min (60 drops) with buretrol or sterile bottle	Yes	- Observe and monitor for adverse reactions
PRIMARY IV BAG	N/A	N/A	N/A	N/A	N/A
IM or SC	N/A	N/A	N/A	N/A	N/A

COMPATIBILITIES/INCOMPATIBILITIES:

- To minimize risk of thrombotic complications, the circulating fibrinogen level should not be raised beyond the lower limit of normal, particularly if additional risk factors (liver disease, coronary heart disease, myocardial infarction, estrogen therapy, pregnancy) are present
- In these patients, simultaneous antithrombotic prophylaxis with ATIII and/or heparin is recommended
- Fibrinogen Concentrate should not be infused together with other intravenously administered drugs(Reference)
- Fibrinogen Concentrate may cause fetal harm when administered to a pregnant woman or if it can affect reproduction capacity(evidence not available)
- As the quantity of sodium in the maximum daily dose may exceed 200 mg it may be harmful to people on a low sodium diet.

ADVERSE EFFECTS:

- Hypersensitivity reactions may occur (e.g. fever, urticarial rashes, nausea, retching, dyspnea, fall in blood pressure, anaphylactic shock) which necessitates the interruption of the replacement therapy

MANAGEMENT OF ADVERSE EFFECTS:

- Notify physician
- Notify Transfusion Medicine
- Mild reactions can be managed with antihistamines
- Severe reactions require immediate intervention following rules of modern shock therapy
- Epinephrine should be available for severe reactions

NOTES:

- in the course of treatment, the development of a circulating inhibitor directed against the infused factor is possible
- Manufactured by IMMUNO
- Distributed by Canadian Blood Services

Documentation

Issue transfuse sheets or requisitions with lot numbers must be included in patient's chart
Written consent for transfusion must be obtained prior to administration

References

Package Insert-Fibrinogen Concentrate (Human), Vapor Heated, Immuno Ag, November 23, 1994.

Developed By In Consultation With

Transfusion Medicine Operations Group
Hemophilia Nurse Coordinator

REVIEW DATES:

REVISION DATES: