READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

FIBRYGA®
Fibrinogen Concentrate (Human)

Read this carefully before you start taking FIBRYGA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about FIBRYGA.

What is FIBRYGA used for?

FIBRYGA is used for the treatment of acute bleeding episodes and perioperative prophylaxis in children and adults with congenital afibrinogenemia and hypofibrinogenemia.

How does FIBRYGA work?

FIBRYGA is a human fibrinogen presented as a powder for solution for intravenous administration (i.e. infusion into a vein). Fibrinogen is a normal constituent of the human blood and supports the blood coagulation of your body. Adequate doses of FIBRYGA may restore abnormally low fibrinogen levels to levels necessary for controlling bleeding.

What are the ingredients in FIBRYGA?

Medicinal ingredients: Fibrinogen (Human)
Non-medicinal ingredients: Sodium chloride, Sodium citrate dihydrate, Glycine, L-Arginine hydrochloride

FIBRYGA comes in the following dosage forms:

FIBRYGA is a powder for solution for intravenous injection and comes in the following dosage forms: 1g

Do not use FIBRYGA if:

- you are allergic to human fibrinogen or any of the other ingredients contained in FIBRYGA.
- you have experienced allergic reactions to FIBRYGA in the past.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FIBRYGA. Talk about any health conditions or problems you may have, including:

- Allergic reactions (e.g. reddening of the skin, skin rash, itching, fall in blood pressure, difficulty in breathing)
- General symptoms (e.g. chills, fever, nausea, vomiting)

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with FIBRYGA:

FIBRYGA should not be mixed with other products.

How to take FIBRYGA:

FIBRYGA is injected into a vein. The product should not be used if it looks cloudy or is leaking. It should be warmed up to room or body temperature before use. Discard any remaining contents after use. Do not use the product after its expiry date (printed on the bottle).

Usual dose:

Your doctor will determine the dose(s) of FIBRYGA. The dose and dosage regimen is dependent on the indication and may need to be individualised for each patient. Doses may be adjusted over time to achieve the desired clinical response and plasma fibrinogen levels.

Overdose:

No cases of overdose with human fibrinogen products have been reported.

If you think you have taken too much FIBRYGA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using FIBRYGA?

- The following side effects have been observed in studies with FIBRYGA: a case of mild pyrexia and two cases of mild skin reactions.

The following side effects have been observed for other fibrinogen products and may potentially also occur after FIBRYGA administration:

- Allergic/ anaphylactic reactions: anaphylaxis, dyspnea, rash, tachypnea, hypotension, shock and tachycardia
- Cardiovascular: thromboembolism, pulmonary embolism
- General: chills, fever, nausea, vomiting

If any of the above listed symptoms occur, are severe or if they worry you, talk to your doctor or pharmacist. These are not all the possible side effects you may feel when taking FIBRYGA. For any unexpected effects while taking FIBRYGA, contact your doctor or pharmacist.
If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Patient Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

    Postage paid labels and the Patient Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store at +2 °C to +25°C for up to 36 months.
Do not freeze. Protect from light. Discard any remaining contents after use. Do not use after expiry date.

Keep out of reach and sight of children.

If you want more information about FIBRYGA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website http://www.octapharma.ca, or by calling 1-888-438-0488.

This leaflet was prepared by Octapharma Pharmazeutika Produktionsges.m.b.H

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