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Canada

Humate-P® Fact Sheet

(Antihemophilic Factor/von Willebrand Factor Complex), Dried, Pasteurized

Product Description

Humate-P® is a stable, purified, sterile, lyophilized concentrate of Antihemophilic Factor (AHF) (Human) and von Willebrand Factor (Human) for the treatment of patients with classical hemophilia (hemophilia A) and von Willebrand disease (vWD).

Humate-P® is the **only** factor concentrate that is currently approved in Canada for the treatment of vWD.

Indications

Humate-P® is indicated for hemophilia A in adult patients for treatment and prevention of bleeding, and vWD in adult and pediatric patients for treatment of spontaneous and trauma-induced bleeding episodes in severe vWD, and in mild and moderate vWD where use of desmopressin is known or suspected to be inadequate. Humate-P® is also indicated to prevent excessive bleeding (i.e. bleeding that exceeds the expected blood loss under a given condition) during and after surgery in adult and pediatric patients.

Mechanism of Action

Decreased production of the von Willebrand protein and blood factor VIII combined with a blood platelet abnormality prohibits blood from clotting properly, causing excessive bleeding. Humate-P® replaces the missing AHF (Antihemophilic Factor) and von Willebrand Factor in the blood, permitting proper clotting.

Method of Administration

Humate-P® is administered (maximally 4 mL/minute) intravenously with an infusion kit or with a suitable injection needle. The dose should be adjusted according to the type of disease and the extent and location of the bleed. Humate-P® does not contain a preservative. Therefore, to assure product sterility, Humate-P® should be administered within three hours after reconstitution.

Clinical Overview

The ability of Humate-P® to assist in the control of bleeding in patients with von Willebrand disease was demonstrated by data from a pivotal study involving 97 vWD patients. Of the bleeding episodes experienced by adult patients who received Humate-P®, at least 95 percent were reported to have an excellent or good response to Humate-P®. Of the bleeding episodes in children with vWD who were treated with Humate-P®, at least 93 percent were reported to have an excellent or good response to the treatment.

Safety Profile

None contraindication is known for Humate-P®, caution is advised in patients with a known allergic reaction to constituents of the preparation.

In clinical trials, Humate-P® was usually tolerated with the following common

side effects: allergic reaction, uticaria, chest tightness, rash, pruritus and edema. Anaphylactic reactions may occur in rare instances. Serious thromboembolic events have been reported in patients with vWD who are treated with coagulation factor replacement therapy. As with all plasma-derived products, the risk of transmission of infectious agents, including viruses, and theoretically, the Creutzfeldt-Jakob disease agent, cannot be completely eliminated. Some viruses, such as parvovirus B19 or hepatitis A, are particularly difficult to remove during the manufacturing process. Parvovirus B19 may most seriously affect pregnant women or immune-compromised individuals and may induce red cell aplasia in some of these patients.

Humate-P® was first introduced in 1981 and for nearly 3 decades of clinical use there has been no documented evidence of viral transmissions with Humate-P®.[1]

For complete risk / benefit profile as well as the full prescribing information of Humate-P® please refer to the current Product Monograph / Prescribing Information, available on our website at www.cslbehring.ca.

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Reference

[1] G. Auerswald: Haemate® P / Humate P® for the treatment of von Willebrand disease: considerations for the use and clinical experience. Haemophilia 2008; 14, (suppl.5), 39-46).