March 2023

Public assessment summary report

Name of the Finished Pharmaceutical Product	OCTANATE 500, 500 IU powder and solvent for solution for injection OCTANATE 1000, 1000 IU powder and solvent for solution for injection
Manufacturer of the Finished Product	Octapharma AB Sweden Company name: Octapharma AB Address: 112 75 Stockholm Country: Sweden Telephone: +46 8 566 43170 Telefax: +46 8 566 43045 EMail: alex.scheepers@octapharma.se
License holder	OCTAPHARMA AG Seidenstrasse 2 CH-8853 Lachen Switzerland
Active Pharmaceutical Ingredient (API)	Human coagulation factor VIII

1. Introduction

Based on review of quality, safety and efficacy data through the abbreviated approval procedure, the authority granted a marketing authorization for OCTANATE 500 and OCTANATE 1000.

OCTANATE is indicated for treatment and prevention of bleeding episodes in patients with hemophilia A (congenital or acquired FVIII deficiency), including previously treated patients (PTPs), previously untreated patients (PUPs) and patients undergoing major and minor surgical procedures; and for the treatment of inhibitors by Immune Tolerance Induction (ITI).

2. Assessment of quality

GMP compliance of the API manufacture was demonstrated by document review. The necessary waiver for cGMP of the finished pharmaceutical product manufacturer has been carried out. Marketing authorization was granted by the stringent regulatory authority (SRA) and appropriate verification of marketing authorization was performed.

Stability testing:
It is confirmed that the finished product stability studies were conducted in the container closure system proposed for the marketing of the product in accordance with the current medicine registration guideline of Ethiopia.

3. Conclusion

Based on assessment of administrative and technical document, it is considered that the benefit–risk profile of OCTANATE 500 and OCTANATE 1000 are acceptable for the following indications: for the treatment and prevention of bleeding episodes in patients with hemophilia A (congenital or acquired FVIII deficiency), including previously treated patients (PTPs), previously untreated patients (PUPs) and patients undergoing major and minor surgical procedures; and for the treatment of inhibitors by Immune Tolerance Induction (ITI).