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Botulism Clinical Experience and Update

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Abstract : BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)] anti-toxin is a mixture of equine immune globulin fragments indicated for the treatment of symptomatic botulism in adult and pediatric patients. The effectiveness of BAT anti-toxin is based on efficacy studies conducted in animal models. A general explanation of the pivotal animal studies, post market surveillance and outcomes of an observational patient registry for patients treated with BAT product distributed in the USA is briefly discussed. Overall it took 20 animal studies for two well-designed and appropriately powered pivotal efficacy studies – one in which the effectiveness of BAT was assessed against all 7 serotypes in the guinea pig, and the other where efficacy is confirmed in the Rhesus macaque using Serotype A. Clinical Experience for BAT to date involves approximately 600 adult and pediatric patients with suspected botulism. In pre-licensure, patient data was recorded under the US CDC expanded access program (259 adult and pediatric patients between 10 days to 88 years of age). In post licensure, greater than 350 patients to date have received BAT and been followed up by enhanced expanded access program. The analysis of the post market surveillance data provided a unique opportunity to demonstrate clinical benefit in the field study required by the animal rule. While the animal rule is applied because human efficacy studies are not ethical or feasible, a post-marketing requirement is to conduct a study to evaluate safety and clinical benefit when circumstances arise and demonstrate the favourable benefit-risk profile that supported licensure.

Keywords : botulism, threat, clinical benefit, observational patient registry
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