21 July 2016
EMA/CHMP/487260/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sialanar

glycopyrronium bromide

On 21 July 2016 the Committee for Medicinal Products for Human Use (CHMP), following a re-examination procedure, adopted a positive opinion, recommending the granting of amarketing authorisation for the medicinal product Sialanar, intended for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling). The applicant for this medicinal product is Proveca Limited.

Sialanar will be available as a 320 micrograms /mloral solution of glycopyrronium (400 micrograms/ml glycopyrronium bromide). The active substance of Sialanar is glycopyrronium bromide (ATC code: A03AB02). Glycopyrronium bromide is a quaternary ammonium antimuscarinic with peripheral effects similar to those of atropine. The peripheral antimuscarinic effect leads to a decreased production of secretions from the salivary glands.

The benefits with Sialanar are its ability to reduce salivary secretions shown in an improvement on mTDS (Modified Teacher's Drooling Scale) as well as in investigator and caregiver global assessment.

The most common side effects are anticholinergic adverse reactions related to the gastrointestinal system such as dry mouth, constipation, diarrhoea and vomiting, all of which occurred at a rate of ≥15% in placebo controlled trials. Other side effects related to the anticholinergic effects, which occurred at a rate of ≥15%, include urinary retention, flushing and nasal congestion.

The full indication is: "Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders."

It is proposed that Sialanar be prescribed by physicians experienced in the treatment of paediatric patients with neurological disorders. Due to limited long term safety data, the treatment duration should be kept as short as possible and closely monitored.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact