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Questions and answers

Update of 26 May 2016:

The company that applied for a marketing authorisation for Sialanar has requested a re-examination of the CHMP's April 2016 opinion. The CHMP will now re-examine its opinion and issue a final recommendation.

Refusal of the marketing authorisation for Sialanar (glycopyrronium bromide)

On 28 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Sialanar, intended for the treatment of persistent drooling in children and adolescents with neurological conditions.

The company that applied for authorisation is Proveca Limited. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Sialanar?

Sialanar is a medicine that contains the active substance glycopyrronium bromide. It was to be available as an oral solution (to be taken by mouth).

What was Sialanar expected to be used for?

Sialanar was expected to be used to treat persistent drooling caused by the inability to control saliva spillage as well as excessive salivation. It was intended for children and adolescents with neurological conditions, such as cerebral palsy, epilepsy and neurodegenerative diseases.

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How is Sialanar expected to work?

The active substance in Sialanar, glycopyrronium bromide, works by blocking receptors in the salivary glands known as muscarinic receptors. These receptors trigger the production of saliva when activated by the nerves from the brain. By blocking the receptors, the medicine is expected to help reduce the amount of saliva produced by the glands and so reduce the risk of drooling.

What did the company present to support its application?

The main data supporting the application came from two published studies, which compared glycopyrronium bromide with placebo (a dummy treatment) in 77 children with neurological conditions and severe drooling. These studies measured improvements in patients' drooling symptoms using a standard rating scale known as mTDS (modified teachers drooling scale).

What were the CHMP's main concerns that led to the refusal?

In recommending a refusal of marketing authorisation, the CHMP noted that there was a lack of adequate data on the medicine's risks as well as insufficient toxicology data from non-human studies. As a consequence, the data provided were not enough to show that glycopyrronium bromide has been used with an acceptable level of safety to treat persistent drooling in patients with neurological conditions. Finally, the CHMP noted that Sialanar has not been shown to improve quality of life.

The Committee therefore concluded that the benefits of Sialanar did not outweigh its risks and recommended that the marketing authorisation be refused.

What consequences does this refusal have for patients in clinical trials or compassionate use programmes?

There are no consequences for patients that may be enrolled in clinical trials or compassionate use programmes with glycopyrronium bromide.

If you are in a clinical trial or compassionate use programme and need more information about your treatment, contact the doctor who is giving it to you.