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EPAR summary for the public

Sialanar

glycopyrronium bromide

This is a summary of the European public assessment report (EPAR) for Sialanar. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Sialanar.

For practical information about using Sialanar, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sialanar and what is it used for?

Sialanar is a medicine for treating severe drooling of saliva in children and adolescents (aged 3 years and above) with conditions affecting the nervous system, such as cerebral palsy, epilepsy and neurodegenerative diseases. It contains the active substance glycopyrronium bromide.

How is Sialanar used?

Sialanar is available as a solution to be taken by mouth three times a day, one hour before or two hours after meals. The starting dose depends on the patient's body weight. The dose is then adjusted according to how the patient responds to the medicine and its side effects.

Sialanar should be prescribed by a doctor with experience in treating children with nervous system conditions and it can only be obtained with a prescription.

How does Sialanar work?

The active substance in Sialanar, glycopyrronium bromide, blocks receptors in the salivary glands known as muscarinic receptors. These receptors trigger the production of saliva when activated by 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 drooling.

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What benefits of Sialanar have been shown in studies?

Two published studies showed that glycopyrronium bromide was effective at reducing drooling in children and adolescents with nervous system conditions, using a standard rating scale known as mTDS (where a score of 1 means no drooling and a score of 9 means profuse drooling).

In one of the studies in 38 children and adolescents with severe drooling, around 74% of those taking glycopyrronium bromide after 8 weeks had their scores reduced by 3 points or more compared with 18% of those taking placebo (a dummy treatment).

The second study involved 27 children and adolescents with severe drooling who took either glycopyrronium bromide or placebo for 8 weeks and then had their treatment switched for another 8 weeks. This study focused on the average final drooling scores after 8 weeks of treatment, which were 1.9 in patients on glycopyrronium bromide and 6.3 in patients on placebo.

What are the risks associated with Sialanar?

The most common side effects with Sialanar (which may affect more than 1 in 10 people) are irritability, flushing, blocked nose, reduced secretions in the airways, dry mouth, constipation, diarrhoea, vomiting and inability to completely empty the bladder (urinary retention). For the full list of all side effects reported with Sialanar, see the package leaflet.

Sialanar must not be used in patients with glaucoma (an eye condition), urinary retention, severe kidney impairment or a history of certain intestinal conditions or myasthenia gravis (a condition affecting muscles). It must also not be used in patients who are pregnant or are taking potassium chloride tablets or capsules or medicines which have anticholinergic effect. For the full list of restrictions with Sialanar, see the package leaflet.

Why is Sialanar approved?

Glycopyrronium bromide is well established in the EU as a treatment for drooling, and published studies show that it is effective in treating severe drooling in children and adolescents with nervous system conditions which can affect their quality of life. With regard to its risks, the side effects that occur with glycopyrronium bromide can be managed by adequately monitoring patients and adjusting the dose.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that benefits of Sialanar outweigh its risks and recommended that it be granted marketing authorisation in the EU.

What measures are being taken to ensure the safe and effective use of Sialanar?

To help prescribers and carers use the medicine as safely as possible, the company that markets Sialanar will provide them with educational material containing information on how to use the medicine properly and manage its side effects.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Sialanar have also been included in the summary of product characteristics and the package leaflet.

Other information about Sialanar

The European Commission granted a marketing authorisation valid throughout the European Union for Sialanar on 15 September 2016.

The full EPAR for Sialanar can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Sialanar, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2016.