SIALANAR ORAL SOLUTION

CHECKLIST FOR HEALTHCARE PROFESSIONALS

Proveca

Checklist For Healthcare Professionals

Sialanar (glycopyrronium 320µg/ml) Oral Solution

Risk minimisation of anticholinergic adverse reactions

Anticholinergic adverse reactions associated with the use of Sialanar may be dose dependent and difficult to assess in a disabled child.

Sialanar is approved for symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.

Sialanar should be prescribed by physicians specialised in the treatment of paediatric patients with neurological disorders, who should also conduct monitoring and dose changes.

Due to the lack of long-term safety data, Sialanar is recommended for short-term intermittent use.

The treating physician should bring to the attention of the patient's parent/caregiver the possible common anticholinergic adverse reactions shown in the checklist to the right that may occur with the use of Sialanar and provide advice on how to recognize and prevent or minimise them.

During the course of the treatment anticholinergic reactions should be assessed in the patient by the physician, indicating the date and result of the assessment using the labels provided, which should be attached to the patient's notes. (The format of the checklist is provided to the right for information.)

It is important to make sure an acurate dose is given each time, in order to prevent harmful effects of Sialanar seen with dosing errors or overdose. In order to give Sialanar safely the dosing table on the *Reminder Card for Caregivers* should be completed by the physician with the proposed dose at each dose change. The *Reminder Card for Caregivers* should be handed to patient's parents/caregivers.

Proveca is conducting a drug utilisation study to assess the value of the educational materials in minimising anticholinergic reactions that may be dose-dependent. Proveca would appreciate your participation in this observational study. For more information and to report your interest in participating in the study, please visit www.sialanarDUS.com.

Checklist for assessment of anticholinergic adverse reactions
Sialanar (glycopyrronium 320µg/ml) Oral Solution

Name of patient: _____

Date of assessment: _____

Anticholinergic reaction	Result of assessment
Urinary retention	
Constipation	
Pneumonia	
Allergic reaction	
Dental caries	
Cardiovascular effects	
CNS effects	
Overheating	

Important information to be brought to the attention of the parent/caregiver

- To give Sialanar exactly as the doctor has directed.
- To check with the treating doctor if parent/caregiver is not sure about the right dose.
- To give Sialanar at least one hour before or two hours after meals.
- To avoid giving Sialanar with a high fat meal as it reduces the amount of medicine absorbed.
- Obligation to measure the dose of Sialanar using the special measuring device (oral syringe) provided, and check the level on the syringe.
- Not to increase the dose without the doctor's permission.
- To stop giving Sialanar and seek urgent medical advice if any of the following adverse reactions occur:
  - Constipation
  - Urinary retention
  - Pneumonia
  - Allergic reaction
- To inform that adverse reactions can sometimes be difficult to recognise in patients with neurological problems who cannot easily express how they feel. To decrease the dose to the previous one and contact the treating doctor if the parent/caregiver thinks that a troublesome adverse reaction is occurring after increasing a dose. To talk to their doctor if they are unsure about whether the child is experiencing any adverse reaction.
- To avoid exposing the patient to hot or very warm weather to prevent overheating and the possibility of heat stroke. To check with the child's doctor during hot weather to see if the dose of Sialanar should be reduced.
- To ensure adequate daily dental hygiene and regular dental health checks to reduce the risk of dental caries.
- If the child seems unwell check the child's pulse rate and report very slow or very fast heart rate.
- To look for changes in the general wellbeing or behaviour since the child cannot always express how they feel and tell the treating healthcare professional.

Additional points to emphasise

- To report any adverse reactions, including those not listed.
- To seek urgent medical advice immediately if the child is given too much Sialanar, even if the child seems well.
- To tell the child's doctor if the child is taking, has recently taken or might take any other medicines. To consult with the prescribing doctor at no longer than 3 monthly intervals to ensure that Sialanar is still an appropriate treatment for the child.
- To read the Patient Information Leaflet.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

For more detailed information on Sialanar read the Summary of Product Characteristics.

For further information or enquiries about Sialanar E-mail: medinfo@proveca.com

Marketing Authorisation Holder: Proveca Pharma Limited, 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland.

This leaflet was last revised in April 2022.