Package Leaflet: Information for the user

Sialanar 320 micrograms/ml oral solution
glycopyrronium

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sialanar is and what it is used for

Sialanar contains the active substance glycopyrronium.
Glycopyrronium belongs to a group of medicines known as quaternary ammonium anticholinergics, which are agents that block or reduce the transmission between nerve cells. This reduced transmission can de-activate the cells that produce saliva.

Sialanar is used to treat excessive production of saliva (sialorrhoea) in children and adolescents aged 3 years and older.

Sialorrhoea (drooling or excessive salivation) is a common symptom of many diseases of the nerves and muscles. It is mostly caused by poor control of muscles in the face. Acute sialorrhoea may be associated with inflammation, dental infections or infections of the mouth.

Sialanar acts on the salivary glands to reduce production of saliva.

2. What you need to know before you give Sialanar

Do not give Sialanar if your child or adolescent:
- is allergic to glycopyrronium or any of the other ingredients of this medicine (listed in section 6)
- is pregnant or breast feeding
- has glaucoma (raised pressure in the eye)
- is unable to completely empty the bladder (urinary retention)
- has severe kidney disease
- has an obstruction of the stomach (pyloric stenosis) or bowel causing vomiting
- has diarrhoea (frequent, loose watery stools)
- has ulcerative colitis (inflammation of the intestine)
- stomach ache and swelling (paralytic ileus)
- has myasthenia gravis (muscle weakness and tiredness)

– is taking any of the following medicines (see section Other medicines and Sialanar):
potassium chloride solid oral dose;
anticholinergic medicines.

Warnings and precautions

Talk to your doctor or pharmacist before using Sialanar if your child has:
- heart disease, heart failure, irregular heartbeats or high blood pressure
- digestive disorders (constipation; chronic heartburn and indigestion)
- a high temperature (fever)
- inability to sweat normally
- kidney problems or difficulty passing urine
- abnormal blood brain barrier (the layer of cells surrounding the brain)

If you are not sure if any of the above applies to your child, talk to a doctor or pharmacist before giving Sialanar.

The carer should stop treatment and seek advice from the prescriber in the event of:
- pneumonia
- allergic reaction
- urinary retention
- changes in behaviour
- constipation
- fever

Avoid exposing the child to hot or very warm temperature (hot weather, high room temperature) to avoid over heating and the possibility of heat stroke. Check with the child's doctor during hot weather to see if the dose of Sialanar should be reduced.

Reduced salivation can increase the risk of dental disease therefore the child's teeth should be brushed daily and they should have regular dental health checks.

Children with kidney problems may be given a lower dose.

Check the child's pulse if they seem unwell. Report a very slow or very fast heart rate to their doctor.

Long-term use
The long-term efficacy and safety of Sialanar has not been studied beyond 24 weeks of use. Continued use of Sialanar should be discussed with the child's doctor every 3 months to check that Sialanar is still right for the child.

Children under 3 years
Do not give this medicine to children under 3 years of age because it is formulated as an oral formulation and a dose specifically for use in children and adolescents aged 3 years and older.

Other medicines and Sialanar
Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

In particular taking Sialanar with the following medicines can affect the way Sialanar or the listed medicine works or can increase the risk of side effects:
- **potassium chloride** solid oral dose (see section above "Do not give Sialanar if the child or adolescent:")
- **anticholinergic medicines** (see section above "Do not give Sialanar if the child or adolescent:")
- **antispasmodics** used to treat sickness or vomiting e.g. domperidone and metaclopramide
- **topiramate** used to treat epilepsy
- **antihistamines**, used to treat some allergies

- **neuroleptics/antipsychotics** (clozapine, haloperidol, phenothiazine), used to treat some mental illnesses
- **skeletal muscle relaxants** (botulinum toxin)
- **antidepressants** (tricyclic antidepressants)
- **opioids** used to treat severe pain
- **corticosteroids**, used to treat inflammatory diseases

Talk to your doctor or pharmacist for further information about medicines to avoid whilst taking Sialanar.

Pregnancy and breast-feeding
This medicine is intended for use in children and adolescents. Sialanar must not be given if the patient is pregnant (or could be pregnant), or is breast-feeding (see section 2 'Do not give'). Discuss with the child's doctor whether there is a need for contraception.

Driving and using machines
Sialanar may affect vision and co-ordination. This may affect performance at skilled tasks such as driving, riding a bicycle, or using machines. After receiving Sialanar, the patient should not drive a vehicle, ride a bicycle or use a machine until the effect in their vision and co-ordination has completely recovered. Ask your doctor if you need further advice.

Sialanar contains sodium and benzoate salt (E211)
This medicine contains less than 1 mmol sodium (23 mg) per maximum dose, that is to say essentially 'sodium free'. This medicine contains 2.3 mg benzoate salt (E211) in each ml.

3. How to use Sialanar

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Children and adolescents 3 years to less than 18 years:
Your doctor will decide the correct dose of Sialanar. The initial dose will be calculated based on the weight of the child. Dose increases will be decided by the child's doctor, using the table below as a guide, and will depend on both the effect of Sialanar and any side effects the patient is experiencing (this is why several dose levels appear in the table below). Section 4 includes possible side effects related to the use of Sialanar. These should be discussed with the child's doctor at all medical consultations, including those for dose increases and decreases, and at any other time should you be concerned.

The child should be monitored at regular intervals (at least every 3 months) to check that Sialanar is still the right treatment for them.

Weight	Dose level 1	Dose level 2	Dose level 3	Dose level 4	Dose level 5
kg	ml	ml	ml	ml	ml
13-17	0.6	1.2	1.8	2.4	3.0
18-22	0.8	1.6	2.4	3.2	4.0
23-27	1.0	2.0	3.0	4.0	5.0
28-32	1.2	2.4	3.6	4.8	6.0
33-37	1.4	2.8	4.2	5.6	6.0
38-42	1.6	3.2	4.8	6.0	6.0
43-47	1.8	3.6	5.4	6.0	6.0
≥48	2.0	4.0	6.0	6.0	6.0

Give the dose prescribed by your doctor to the child three times each day.
The dose should be given 1 hour before meals or 2 hours after meals.
It is important that the dose is given at consistent times in relation to food intake. Do not give with high fat foods.

Route of administration
Sialanar should be taken by mouth.

Instructions for use

How to use the oral syringe
Remove the child-resistant closure from the bottle.
Insert the syringe adaptor with the hole into the neck of the bottle (this may have been done already by the pharmacist).
Insert the end of the oral syringe into the syringe adaptor and ensure it is secure.

Hold the oral syringe in place and turn the bottle upside down. Gently pull down the plunger to the correct level (see the tables for the correct dose). Check you have the correct level. The maximum volume of the highest dose is 6 ml.

Turn the bottle upright.
Remove the oral syringe by holding the bottle and twisting the oral syringe gently.

Place the oral syringe inside the child's mouth and press the plunger slowly to gently release the medicine.

After use, leave the syringe adaptor in the neck of the bottle.
Replace the closure.

The oral syringe should be gently washed with warm water and allowed to dry after each use (i.e. three times per day). Do not use a dishwasher.

If your child is given the medicine through a feeding tube, flush the tube with 10 ml of water after you have given the medicine.

If you give more Sialanar than you should
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.

Check that you have drawn up the correct level on the syringe before giving Sialanar.

Seek medical advice immediately if the child is given too much Sialanar, even if the child seems well.

If you forget to give Sialanar
Give the next dose when it is due. Do not give a double dose to make up for the forgotten dose.

If you stop giving Sialanar to your child
Withdrawal effects are not expected when stopping Sialanar. The child's doctor may decide to stop treatment with Sialanar if side effects cannot be managed by reducing the dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following serious side effects occur, stop using the medicine and seek urgent medical advice.
- Constipation (difficulty in passing stool) – very common
- Difficulty in passing urine (urinary retention) – very common
- Pneumonia (sever chest infection) - common
- Allergic reaction (rash, itching, red raised itchy rash (hives), difficulty breathing or swallowing, dizziness) – frequency not known

The following side effects may be a sign of severe allergic reaction. If they occur, take the child to the nearest emergency medical facility and take the medicine with you.
- Swelling mainly of the tongue, lips, face or throat (possible signs of angioedema) – frequency not known

Other side effects are:

Very common (may affect more than 1 in 10 people)
- Dry mouth
- Difficulty in passing stools (constipation)
- Diarrhoea
- Being sick (vomiting)
- Flushing
- Nasal congestion
- Unable to completely empty the bladder (urinary retention)
- Reduced secretions in the chest
- Irritability

Common (may affect up to 1 in 10 people)
- Upper respiratory tract infection (chest infection)

- Pneumonia (severe chest infection)
- Urinary tract infection
- Drowsiness (sleepiness)
- Agitation
- Fever (pyrexia)
- Nose bleeds (epistaxis)
- Rash

Uncommon (may affect up to 1 in 100 people)
- Bad breath (halitosis)
- Fungal infection (thrush) of the throat (oesophageal candidiasis)
- Abnormal contractions of the digestive tract when food is ingested (gastrointestinal motility disorder)
- A disorder of the muscles and nerves in the intestine which causes an obstruction or blockage (pseudo-obstruction)
- Widening of the pupil of the eye (mydriasis)
- Involuntary eye movement (nystagmus)
- Headache
- Dehydration
- Thirst in hot weather

Other side effects that occur with anticholinergics but their frequency with glycopyrronium is not known
- allergic reaction (rash, itching, red raised itchy rash (hives), difficulty breathing or swallowing, dizziness)
- severe allergic reaction (angioedema); signs include swelling mainly of the tongue, lips, face or throat
- restlessness; overactivity; short attention span; frustration; mood changes; temper outbursts or explosive behaviour; excessive sensitivity; seriousness or sadness; frequent crying episodes; fearfulness
- insomnia (difficulty in sleeping)
- raised pressure in the eye (which might cause glaucoma); photophobia (sensitivity to light); dry eyes
- slow heart rate followed by rapid heart rate, palpitations and irregular heart beat
- inflammation and swelling of sinuses (sinusitis)
- feeling sick (nausea)
- dry skin
- reduced ability to sweat, which can cause fever and heatstroke
- urgent need to urinate

Side effects can sometimes be difficult to recognise in patients with neurologic problems who cannot easily tell you how they feel.

If you think a troublesome side effect is occurring after increasing a dose, the dose should be decreased to the previous one used and your doctor contacted.

Tell your doctor if you notice any behavioural changes or any other changes in the child.

Reporting of side effects
If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see below).
By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom (Northern Ireland)
Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Sialanar

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.
This medicine must be used within 2 months of first opening the bottle.

Do not use this medicine after the expiry date, which is stated on the label after EXP: The expiry date refers to the last day of that month.

Sialanar should not be used if the packaging has been opened or damaged.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sialanar contains
The active substance is glycopyrronium.
Each ml of solution contains 400 micrograms glycopyrronium bromide equivalent to 320 micrograms of glycopyrronium.
The other ingredients are sodium benzoate (E211) (see section 2 "Sialanar contains sodium and benzoate salt"), raspberry flavouring (containing propylene glycol E1520), sucralose (E955), citric acid (E330) and purified water.

What Sialanar looks like and contents of the pack
Sialanar oral solution is a clear, colourless liquid. It is supplied in a 60 ml or 250 ml amber glass bottle in a cardboard carton. Each carton contains one bottle, one 8 ml oral syringe and one syringe adaptor. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Proveca Pharma Ltd
2 Dublin Landings
North Wall Quay
Dublin 1
Ireland

Manufacturer
Centre Spécialités Pharmaceutiques (CSP),
Z.A.C. des Suzots,
35 rue de la Chapelle,
63450 Saint Amant Tallende,
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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.