

PATIENT and CAREGIVER INFORMATION

Glycopyrrolate oral solution

Please read the Patient and Caregiver Information that comes with Glycopyrrolate oral solution before you start giving it to your child, and each time you get a refill. This leaflet does not take the place of talking with your doctor about your child's medical condition or treatment.

What is Glycopyrrolate oral solution?

Glycopyrrolate oral solution is a prescription medicine used in children with medical conditions that cause too much (abnormal) drooling.

Who should not take Glycopyrrolate oral solution?

Do not give Glycopyrrolate oral solution to anyone who:

- has problems urinating
- has a bowel problem called paralytic ileus
- lacks normal bowel tone or tension
- has severe ulcerative colitis or certain other serious bowel problems with severe ulcerative colitis
- has myasthenia gravis

What should I tell my doctor before giving Glycopyrrolate oral solution to my child?

Tell your doctor if your child:

- has any allergies
- has any stomach or bowel problems, including ulcerative colitis
- has any problems with constipation
- has thyroid problems
- has high blood pressure
- has heart problems or abnormal heart beats
- has a hiatal hernia with gastroesophageal reflux disease (GERD)
- has any eye problems
- has any problems urinating
- has any other medical conditions
- is pregnant or plans to become pregnant. It is not known if Glycopyrrolate oral solution can harm an unborn baby.
- is breastfeeding or plans to breastfeed. It is not known if Glycopyrrolate oral solution passes into breast milk and if it can harm the baby.

Tell your doctor about all of the medicines that your child takes, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicine may affect the way

Glycopyrrolate oral solution works, and Glycopyrrolate oral solution may affect how some other medicines work.

How should I give Glycopyrrolate oral solution?

- Give Glycopyrrolate oral solution exactly as prescribed by your child's doctor.
- Give Glycopyrrolate oral solution 1 hour before or 2 hours after meals.
- Your doctor will tell you how much (millilitres or mLs) of Glycopyrrolate oral solution to give your child.
- Do not change the dose of Glycopyrrolate oral solution unless your doctor tells you to.
- You must measure the dose of Glycopyrrolate oral solution before giving it to your child. Use a special marked dose measuring cup (available at most pharmacies) to measure the right dose of Glycopyrrolate oral solution.
- To help make sure that your child swallows the dose, you should use an oral syringe to give the child each dose of Glycopyrrolate oral solution, after you measure the dose needed with a dose measuring cup. Oral syringes are also available at most pharmacies.
- If you have questions about how to measure the dose or how to use an oral syringe, ask your pharmacist or doctor.
- The dose of Glycopyrrolate oral solution that is needed to control drooling may be different for each child. Glycopyrrolate oral solution is usually started at a low dose, and slowly increased as directed by your doctor. This slow increase in dose continues until the best dose for your child is reached, to control drooling.
- During this time it is important to stay in close contact with your child's doctor, and tell the doctor about any side effects that your child has. See "What are the possible side effects of Glycopyrrolate oral solution?"

What should I avoid while taking Glycopyrrolate oral solution?

- Glycopyrrolate oral solution may cause sleepiness or blurred vision. Do not drive a car, operate heavy machinery, or do other dangerous activities while taking Glycopyrrolate oral solution.
- Avoid overheating. See "What are the possible side effects of Glycopyrrolate oral solution?"

What are the possible side effects of Glycopyrrolate oral solution?

Glycopyrrolate oral solution can cause serious side effects including:

- **Constipation.** Constipation is common with Glycopyrrolate oral solution. Tell your doctor if your child strains with bowel movements, goes longer between bowel movements, cannot have a bowel movement, or their stomach is firm and large. The dose of Glycopyrrolate oral solution may need to be decreased or stopped.
- **Diarrhea and intestinal blockage.** Diarrhea can be an early symptom of a blockage in the intestine. This is especially true if your child has a colostomy or ileostomy. Tell your doctor if your child has any diarrhea while taking Glycopyrrolate oral solution.

- **Problems with control of body temperature (overheating or heat stroke).** Glycopyrrolate oral solution can cause your child to sweat less. Your child can become overheated, and develop heat stroke if they are in an area that is very hot. Avoid overheating. Call your doctor right away if your child becomes sick and has any of these symptoms of heatstroke:
 - hot, red skin
 - decreased alertness or passing out (unconsciousness)
 - fast, weak pulse
 - fast, shallow breathing
 - increased body temperature (fever)

The most common side effects of Glycopyrrolate oral solution include:

- dry mouth
- vomiting
- flushing of the face or skin
- nasal congestion
- headache
- swollen sinuses (sinusitis)
- upper respiratory tract infection
- problems urinating, difficulty starting urination

Tell your doctor if your child has any side effect that concerns you or that does not go away. These are not all the possible side effects of Glycopyrrolate oral solution.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Glycopyrrolate oral solution?

Store Glycopyrrolate oral solution between 68°F to 77°F (20°C to 25°C).

Keep Glycopyrrolate oral solution out of the reach of children.

General information about Glycopyrrolate oral solution:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Glycopyrrolate oral solution for a condition for which it was not prescribed. Do not give Glycopyrrolate oral solution to other people even if they have the same condition. It may harm them.

This leaflet summarizes the most important information about Glycopyrrolate oral solution. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Glycopyrrolate oral solution that is written for health professionals.

For more information about Glycopyrrolate oral solution, please contact Granules Pharmaceuticals Inc., at 1-877-770-3183.

What are the ingredients in Glycopyrrolate oral solution?

Active Ingredient: Glycopyrrolate

Inactive Ingredients: citric acid anhydrous, natural and artificial cherry flavor, glycerin, methylparaben, propylene glycol, propylparaben, sodium saccharin, sorbitol, trisodium citrate and purified water.

Manufactured by:

Granules Pharmaceuticals Inc.,
Chantilly, VA 20151

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