

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DARTISLA ODT safely and effectively. See full prescribing information for DARTISLA ODT.

DARTISLA ODT (glycopyrrolate) orally disintegrating tablets
Initial U.S. Approval: 1961

INDICATIONS AND USAGE

DARTISLA ODT is an anticholinergic indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. (1)

Limitations of Use:

Not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established. (1)

DOSAGE AND ADMINISTRATION

Important Dosing Information (2.1)

- Patients receiving the 2 mg dosage strength of another oral tablet dosage form of glycopyrrolate may be switched to DARTISLA ODT.
- Not recommended for patients initiating treatment or receiving maintenance treatment with a lower dosage strength of another oral glycopyrrolate product (e.g., tablet strength of 1 mg).

Recommended Dosage (2.2)

- The recommended dosage is 1.7 mg given two or three times daily administered on top of the tongue; allow to disintegrate and swallow without water.
- The maximum recommended daily dosage is 6.8 mg.
- Administer at least one hour before or two hours after food.
- Use the lowest effective dosage to control symptoms; switch patients who can be titrated to a lower dose to another oral tablet dosage form of glycopyrrolate.

DOSAGE FORMS AND STRENGTHS

- Orally Disintegrating Tablets: 1.7 mg of glycopyrrolate (3)

CONTRAINDICATIONS

- Patients at risk for anticholinergic toxicity due to various underlying medical conditions. (4, 5.1, 5.2, 5.3)
- Hypersensitivity to glycopyrrolate or the inactive ingredients. (4)

WARNINGS AND PRECAUTIONS

- **Precipitation of Acute Glaucoma:** May increase intraocular pressure; if symptoms occur, discontinue use, and promptly seek medical care. (4, 5.1)
- **Partial or Complete Mechanical Intestinal Obstruction:** Diarrhea may be an early symptom, especially in patients with ileostomy or colostomy. If obstruction is suspected, discontinue use and evaluate the patient for obstruction. (4, 5.2)

- **GI Adverse Reactions Due to Decreased GI Motility:** Delayed gastric emptying, constipation, and intestinal pseudo-obstruction may occur and precipitate or aggravate paralytic ileus and toxic megacolon; not recommended for use with anticholinergics or other medications that decrease GI peristalsis. (4, 5.3, 7.1)
- **Cognitive and Visual Adverse Reactions:** May impair mental and/or physical function. Inform patients not to operate motor vehicles or perform other hazardous tasks until reasonably certain they are not adversely affected; discontinue use if signs or symptoms develop. (5.4, 7.1)
- **Heat Prostration at High Environmental Temperatures:** Heat prostration resulting in fever and heat stroke can occur, especially in geriatric patients. Avoid exposure to hot or very warm environmental temperatures. (5.5, 5.7)
- **Other Conditions Exacerbated by Anticholinergic Adverse Reactions:** Use is not recommended in patients with autonomic neuropathy, hyperthyroidism, cardiac disease, hiatal hernia, etc. (5.6, 7.1)
- **Increased Risk of Anticholinergic Adverse Reactions in Geriatric Patients:** Complications include urinary retention, bowel obstruction, heat prostration, arrhythmias, delirium, and falls or fractures. Not recommended in geriatric patients and may be contraindicated in some patients with underlying medical conditions. (4, 5.7, 8.5)

ADVERSE REACTIONS

Adverse reactions include blurred vision, drowsiness, decreased sweating, flushing, vomiting, constipation, dry mouth, tachycardia, and urinary retention. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Edenbridge Pharmaceuticals, LLC at 1-877-381-3336 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- **Other Anticholinergic Drugs:** Concomitant use is not recommended. (5.3, 5.4, 5.6, 7.1)
- **Drugs with Altered Absorption due to Decreased GI Motility:** Concomitant use is not recommended. (7.2)
- **GI Toxicity with Solid Oral Dosage Forms of Potassium Chloride:** Concomitant use is not recommended. (7.3)

USE IN SPECIFIC POPULATIONS

- **Renal Impairment:** Monitor patients with renal impairment; if anticholinergic adverse reactions occur, discontinue use. (8.6)

See 17 for PATIENT COUNSELING INFORMATION.

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*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

DARTISLA ODT is indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.

Limitations of Use

DARTISLA ODT is not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established.

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosing Information

- Patients receiving the 2 mg dosage strength of another oral tablet dosage form of glycopyrrolate may be switched to the 1.7 mg dosage strength of DARTISLA ODT [*see Dosage Forms and Strengths (3) and Clinical Pharmacology (12.3)*].
- DARTISLA ODT is not recommended for patients in whom a lower dosage strength of another oral glycopyrrolate product (e.g., tablet strength of 1 mg) is appropriate for initial or maintenance treatment because the dosage strength of DARTISLA ODT may exceed the recommended initial and maintenance dosage of other oral glycopyrrolate products.


2.2 Recommended Dosage

- The recommended dosage of DARTISLA ODT is 1.7 mg given two or three times daily administered on top of the tongue. Allow the tablet to disintegrate and swallow without water [*see Clinical Pharmacology (12.3)*].
- The maximum recommended daily dosage of DARTISLA ODT is 6.8 mg.
- Administer DARTISLA ODT at least one hour before or two hours after food [*see Clinical Pharmacology (12.3)*].
- Use the lowest effective dosage of glycopyrrolate to control symptoms. Switch patients who can be titrated to a lower dose of oral glycopyrrolate to another oral tablet dosage form of glycopyrrolate.

2.3 Administration Instructions

- Use dry hands when opening the blister card and do not open the blister until ready to administer.
- Open the package and peel back the foil on the blister to expose the tablet and gently remove from the blister. Do not push the tablet through the foil.
- Do not break or cut the tablet.
- Immediately place the tablet on the tongue, allow it to disintegrate, and swallow without water.

3 **DOSAGE FORMS AND STRENGTHS**

Orally Disintegrating Tablets: 1.7 mg of glycopyrrolate, white to off-white, round, and debossed with the symbol .

4 **CONTRAINDICATIONS**

DARTISLA ODT is contraindicated in:

- Patients at risk for anticholinergic toxicity due to an underlying medical condition, including:
 - Glaucoma [see *Warnings and Precautions (5.1)*]
 - Obstructive uropathies including prostatic hypertrophy
 - Mechanical obstructive diseases of gastrointestinal tract (e.g., pyloroduodenal stenosis, strictures) [see *Warnings and Precautions (5.2)*]
 - Gastrointestinal motility disorders (e.g., achalasia, paralytic ileus, intestinal atony) [see *Warnings and Precautions (5.3)*]
 - Bleeding gastrointestinal ulcer
 - Active inflammatory or infectious colitis which can lead to toxic megacolon
 - History of or current toxic megacolon
 - Myasthenia gravis
- Patients with a hypersensitivity to glycopyrrolate or any of the inactive ingredients in DARTISLA ODT [see *Adverse Reactions (6)* and *Description (11)*].

5 **WARNINGS AND PRECAUTIONS**

5.1 **Precipitation of Acute Glaucoma**

Glycopyrrolate may cause increased intraocular pressure in patients with glaucoma and reduce the effects of antiglaucoma agents. Instruct patients to discontinue DARTISLA ODT and promptly seek medical care if they experience symptoms of acute angle closure glaucoma (pain and reddening of the eyes accompanied by dilated pupils) [see *Contraindications (4)*].

5.2 **Partial or Complete Mechanical Intestinal Obstruction**

DARTISLA ODT may worsen intestinal mechanical obstruction, and diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. If partial or complete intestinal obstruction is suspected, discontinue use of DARTISLA ODT and evaluate for potential intestinal obstruction [see *Contraindications (4)*].

5.3 **Gastrointestinal Adverse Reactions Due to Decreased Gastrointestinal Motility**

Glycopyrrolate reduces gastrointestinal motility and may result in delayed gastric emptying, constipation, and intestinal pseudo-obstruction and may precipitate or aggravate paralytic ileus and toxic megacolon [see *Contraindications (4)*]. The risk of gastrointestinal adverse reactions is further increased with use of other anticholinergics and other medications that decrease gastrointestinal peristalsis. Monitor patients for symptoms of decreased gastrointestinal motility. Concomitant use of DARTISLA ODT and other anticholinergics or other medications that decrease GI peristalsis is not recommended [see *Drug Interactions (7.2)*].

5.4 Cognitive and Visual Adverse Reactions

Glycopyrrolate may produce drowsiness and blurred vision and impair the mental and/or physical abilities required for the performance of hazardous tasks such as driving a motor vehicle, operating machinery or performing other hazardous work [see *Adverse Reactions (6)*]. Concomitant use of other drugs that have anticholinergic properties may increase these effects [see *Drug Interactions (7.1)*]. Inform patients not to operate motor vehicles or other dangerous machinery or perform other hazardous tasks until they are reasonably certain that DARTISLA ODT does not affect them adversely. Discontinue DARTISLA ODT if signs or symptoms of cognitive or visual impairment develop.

5.5 Heat Prostration at High Environmental Temperatures

In the presence of a high environmental temperature, heat prostration resulting in fever and heat stroke can occur with use of DARTISLA ODT due to decreased sweating, particularly in geriatric patients [see *Adverse Reactions (6)*]. Advise patients to avoid exposure to hot or very warm environmental temperatures when taking DARTISLA ODT. DARTISLA ODT is not recommended in geriatric patients [see *Warnings and Precautions (5.7)*].

5.6 Other Conditions Exacerbated by Anticholinergic Adverse Reactions

DARTISLA ODT is not recommended in patients with other conditions exacerbated by anticholinergic adverse reactions (e.g., autonomic neuropathy, hyperthyroidism, cardiac disease, and hiatal hernia associated with reflux esophagitis) and in patients taking other anticholinergic medications [see *Drug Interactions (7.1)*].

5.7 Increased Risk of Anticholinergic Adverse Reactions in Geriatric Patients

Geriatric patients 65 years of age and older are at increased risk of anticholinergic adverse reactions that may lead to complications of urinary retention, bowel obstruction, heat prostration, arrhythmias, delirium, and falls or fractures. DARTISLA ODT is not recommended in geriatric patients and may be contraindicated in some geriatric patients with underlying medical conditions [see *Contraindications (4)*, *Warnings and Precautions (5.2, 5.5)*, *Adverse Reactions (6)* and *Use in Specific Populations (8.5)*].

6 ADVERSE REACTIONS

The following serious or otherwise important adverse reactions are discussed elsewhere in the labeling:

- Precipitation of Acute Glaucoma [see *Warnings and Precautions (5.1)*]
- Partial or Complete Mechanical Intestinal Obstruction [see *Warnings and Precautions (5.2)*]
- Gastrointestinal Adverse Reactions due to Decreased Gastrointestinal Motility [see *Warnings and Precautions (5.3)*]
- Cognitive and Visual Adverse Reactions [see *Warnings and Precautions (5.4)*]
- Heat Prostration at High Environmental Temperatures [see *Warnings and Precautions (5.5)*]
- Other Conditions Exacerbated by Anticholinergic Adverse Reactions [see *Warnings and Precautions (5.6)*]
- Increased Risk of Anticholinergic Adverse Reactions in Geriatric Patients [see *Warnings and Precautions (5.7)*]

The following adverse reactions associated with the use of glycopyrrolate, or other anticholinergic drugs, were identified in clinical studies or postmarketing reports. Because some of these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiac Disorders: chest, pain, hypertension, tachycardia

Endocrine Disorders: decreased sweating

Eye Disorders: blurred vision, cycloplegia, dilatation of the pupil, increased ocular tension

Gastrointestinal Disorders: bloated feeling, constipation, dry mouth, dysgeusia, nausea, vomiting

Immune System Disorders: anaphylaxis [see *Contraindications (4)*]

Nervous System Disorders: agitation, dizziness, drowsiness, headache, insomnia, mental confusion, nervousness, weakness

Respiratory Disorders: respiratory depression, throat irritation

Renal and Urinary Disorders: urinary hesitancy, urinary retention

Reproductive System and Breast Disorders: impotence, suppression of lactation

Vascular Disorders: flushing

7 DRUG INTERACTIONS

7.1 Other Anticholinergic Drugs

There is potential for an additive interaction between glycopyrrolate and concomitantly used anticholinergic drugs (e.g., tricyclic antidepressants, anti-epileptics, class I antiarrhythmics, anti-spasmodics, amantadine) resulting in increased anticholinergic adverse reactions. Coadministration of antipsychotics with glycopyrrolate may lead to worsening of tardive dyskinesia. DARTISLA ODT is not recommended in patients taking other anticholinergic drugs [see *Warnings and Precautions (5.3, 5.4, 5.6)*].

7.2 Drugs with Altered Absorption due to Decreased Gastrointestinal Motility and Increased Transit Time

Decreased gastrointestinal motility by glycopyrrolate may impact absorption of other drugs leading to increased or decreased drug exposure. DARTISLA ODT is not recommended in patients taking other drugs that are affected by altered gastrointestinal motility [see *Warnings and Precautions (5.3)*].

7.3 Gastrointestinal Toxicity with Solid Oral Dosage Forms of Potassium Chloride

Oral glycopyrrolate may worsen gastrointestinal mucosal injury reported with solid oral dosage forms of potassium chloride due to decreased gastric motility and increased transit time leading to prolonged contact with the gastrointestinal mucosa. DARTISLA ODT is not recommended in patients taking solid oral dosage forms of potassium chloride.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Over decades of use, there is an absence of published data on orally administered glycopyrrolate in pregnant women, including an absence of any reports of a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal studies, at non-maternally toxic doses of oral glycopyrrolate, there were no adverse developmental effects in rats or rabbits. A pre- and post-natal development study of oral glycopyrrolate in rats showed a decrease in pup mean body weight that recovered post nursing, with no other developmental effects observed (*see Data*).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

At non-maternally toxic doses of oral glycopyrrolate there were no effects on embryo-fetal development or toxicity in rats or rabbits. A pre- and post-natal development study of oral glycopyrrolate in rats showed a decrease in pup mean body weight that recovered post nursing, with no other developmental effects observed.

In a published reproductive and developmental study, male and female rats were administered glycopyrrolate in the diet at 0, 32.5, 63 and 130 mg/kg/day for 3 to 5 weeks and through up to three consecutive litters. There was no indication of abnormalities in the pups of treated dams. There was a decreased rate of conception and in survival rate at weaning for all treated animals in a dose-related manner. Diminished rates of conception may be due to diminished seminal secretion [*see Nonclinical Toxicology (13.1)*].

8.2 Lactation

Risk Summary

There are no data on the presence of glycopyrrolate in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. As with other anticholinergic drugs, glycopyrrolate may cause suppression of lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DARTISLA ODT and any potential adverse effects on the breastfed infant from DARTISLA ODT.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Geriatric patients 65 years of age and older may be more sensitive to the anticholinergic adverse reactions of glycopyrrolate leading to complications of urinary retention, bowel obstruction, heat prostration, arrhythmias, delirium, and falls or fractures; therefore, DARTISLA ODT is not recommended in geriatric patients and may be contraindicated in some geriatric patients with underlying medical conditions [see *Contraindications (4) and Warnings and Precautions (5)*].

8.6 Renal Impairment

Glycopyrrolate is substantially excreted by the kidney [see *Clinical Pharmacology (12.3)*]. Monitor patients with renal impairment for anticholinergic adverse reactions [see *Adverse Reactions (6)*]. If anticholinergic adverse reactions occur, discontinue DARTISLA ODT.

10 OVERDOSAGE

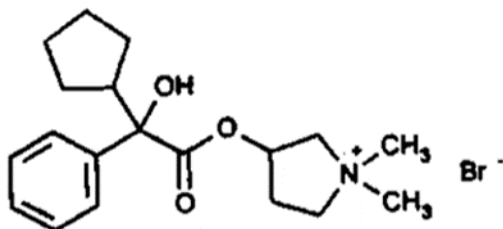
Signs and symptoms of glycopyrrolate overdosage are related to excessive anti-muscarinic anticholinergic activity and are generally peripheral (e.g., flushing, hyperthermia, tachycardia, ileus, urinary retention, loss of ocular accommodation and light sensitivity due to mydriasis), but central nervous system toxicity (agitation, seizures, hyperthermia) may also occur.

If over-exposure occurs, call the Poison Control Center at 1-800-222-1222 for current information on the management of glycopyrrolate poisoning and overdosage.

Management of glycopyrrolate overdosage is based upon presenting signs and symptoms, including close observation for severe or life-threatening complications which may require respiratory and cardiovascular monitoring and support. Consider administration of activated charcoal and/or use of a reversible anticholinesterase as appropriate or recommended by Poison Control.

11 DESCRIPTION

DARTISLA ODT (glycopyrrolate) orally disintegrating tablets contains the synthetic anticholinergic, glycopyrrolate. Glycopyrrolate is a quaternary ammonium compound with the following chemical name: 3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide. The empirical formula for glycopyrrolate is $C_{19}H_{28}BrNO_3$, the molecular weight is 398.3 g/mol, and the structural formula is:



Each DARTISLA ODT contains: glycopyrrolate, USP 1.7 mg as the active ingredient. The inactive ingredients include black cherry, citric acid, fish gelatin (high molecular weight), mannitol, poloxamer 188, purified water and sucralose micronized.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Glycopyrrolate, an anticholinergic (antimuscarinic) agent, inhibits the action of acetylcholine on parietal cells in the stomach and decreases the volume and acidity of gastric secretions.

12.2 Pharmacodynamics

No formal pharmacodynamic studies have been conducted with DARTISLA ODT.

12.3 Pharmacokinetics

Absorption

After DARTISLA ODT administration under fasted conditions, the mean (SD) C_{\max} was 390 (± 237) pg/mL, and the mean AUC_{0-t} and $AUC_{0-\infty}$ was 1862 (± 1116) and 1977 (± 1171) pg·h/mL, respectively. The median time to maximum plasma concentration was 3 hours. After DARTISLA ODT 1.7 mg administration, the C_{\max} and AUC of glycopyrrolate were comparable to an oral 2 mg glycopyrrolate tablet [see *Dosage and Administration (2.2)*].

When DARTISLA ODT was placed in the mouth and immediately swallowed with 240 mL water, the mean C_{\max} and AUC of glycopyrrolate decreased by 24% and 20%, respectively, compared to administration without water [see *Dosage and Administration (2.2)*].

Effect of Food

In healthy adults, a high-fat, high-calorie meal (939 calories, 60% fat) significantly reduced the absorption of glycopyrrolate following administration of DARTISLA ODT 1.7 mg. The mean C_{\max} and AUC were approximately 83% and 77% lower, respectively, than those observed under fasted conditions [see *Dosage and Administration (2.2)*].

Elimination

After DARTISLA ODT 1.7 mg administration, the mean plasma half-life was 2.8 hours.

Specific Populations

Patients with Renal Impairment


In published literature, glycopyrrolate 4 mcg/kg was administered intravenously (DARTISLA ODT is not recommended for intravenous use) in uremic patients undergoing renal transplantation surgery. The mean AUC (10.6 mcg·h/L), and 24-hour urinary excretion (7%) for glycopyrrolate were significantly different from normal healthy adult subjects undergoing general surgery (3.7 mcg·h/L, and 65%, respectively) [see *Use in Specific Populations (8.6)*].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Reproduction studies in rats resulted in diminished rates of conception, in a dose-related manner. Studies in dogs suggest that diminished rates of conception may be due to diminished seminal secretion, which is evident at high doses of glycopyrrolate.

16 HOW SUPPLIED/STORAGE AND HANDLING

DARTISLA ODT is supplied as 1.7 mg glycopyrrolate as a white to off-white, round orally disintegrating tablets debossed with the symbol . Available as:

- NDC 82111-518-01: 30 orally disintegrating tablets per carton. Each carton has 3 blister cards containing 10 orally disintegrating tablets each.

Store at 20°C to 25°C (68°F to 77°F); with excursions between 15°C to 30°C (59°F to 86°F) [USP controlled room temperature].

17 PATIENT COUNSELING INFORMATION

Precipitation of Acute Glaucoma

Advise patient to discontinue DARTISLA ODT and promptly seek medical care if they experience symptoms of acute angle closure glaucoma (pain and reddening of the eyes accompanied by dilated pupils) [see *Warnings and Precautions (5.1)*].

Partial or Complete Mechanical Intestinal Obstruction

Advise patients to contact their healthcare provider if diarrhea occurs, especially in patients with ileostomy or colostomy [see *Warnings and Precautions (5.2)*].

Gastrointestinal Adverse Reactions Due to Decreased Gastrointestinal Motility

Inform patients that DARTISLA ODT may cause adverse reactions related to decreased gastrointestinal motility and to report to their healthcare provider if they experience symptoms such as vomiting, early satiety, abdominal distention, and constipation [see *Warnings and Precautions (5.3)*].

Cognitive and Visual Adverse Reactions

Inform patients that DARTISLA ODT may cause cognitive or visual impairment and not to operate motor vehicles or other dangerous machinery or perform other hazardous tasks until they are reasonably certain that DARTISLA ODT does not affect them adversely. Advise patients to discontinue DARTISLA ODT immediately and contact their healthcare provider if symptoms develop (e.g., drowsiness or blurred vision) [see *Warnings and Precautions (5.4)*].

Heat Prostration at High Environmental Temperatures

Inform patients that DARTISLA ODT can reduce sweating, leading to the possibility of heat exhaustion or heat stroke. Advise patients to avoid exposure to hot or very warm environmental temperatures [see *Warnings and Precautions (5.5)*].

Dosage and Administration Instructions

- Administer DARTISLA ODT at least one hour before or two hours after food [*see Dosage and Administration (2.2)*].
- Use dry hands when handling the blister card and do not open the blister until ready to administer.
- Open the package and peel back the foil on the blister to expose the tablet and gently remove from the blister. Do not push the tablet through the foil.
- Do not break or cut the tablet.
- Immediately place the tablet on the tongue, allow it to disintegrate, and swallow without water [*see Dosage and Administration (2.3)*].

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