FIRST TIME GENERIC APPROVAL

Brand Name	Cuvposa®
Generic Name	glycopyrrolate
Drug Manufacturer	Par Pharmaceutical, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

August 9, 2021

LAUNCH DATE

January 6, 2021

REVIEW DESIGNATION

None

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 204438

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Glycopyrrolate oral solution is an anticholinergic indicated to reduce chronic severe drooling in patients aged 3 to16 years with neurologic conditions associated with problem drooling (e.g., cerebral palsy).

MECHANISMS OF ACTION

Glycopyrrolate is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including salivary glands. It indirectly reduces the rate of salivation by preventing the stimulation of these receptors.

DOSE FORM AND STRENGTH

1 mg/5 mL, oral solution in 16-ounce bottles.

DOSE & ADMINISTRATION

Initiate dosing at 0.02 mg/kg three times daily and titrate in increments of 0.02 mg/kg every 5 to 7 days, based on therapeutic response and adverse reactions.