DURATUSS AC- codeine phosphate, dexbrompheniramine maleate liquid
Poly Pharmaceuticals, Inc.

Duratuss AC

Active ingredients

(in each 5 mL teaspoonful)

Codeine Phosphate 10 mg ..... Antitussive
Dexbrompheniramine Maleate 1 mg ..... Antihistamine

Antihistamine

Antitussive

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- runny nose
- sneezing
- itching of nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to the enlargement of the prostate gland
- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm
- a chronic pulmonary disease or shortness of breath, or children who are taking other drugs
- heart disease
- high blood pressure
- thyroid disease
- diabetes

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- may cause or aggravate constipation

- alcohol, sedatives, and tranquilizers may increase drowsiness effect

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.
- new symptoms occur

If pregnant or breastfeeding ask a health professional before use

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

Do not use this product

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional

conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Directions

Adults 12 and over: 10 mL every 4-6 hours

Not to exceed 60 mL in 24 hours or as directed by a doctor

Children 6-12: 5 mL every 4 hours,

Not to exceed 30 mL in 24 hrs or as directed by a doctor

Children under 6: Consult a doctor

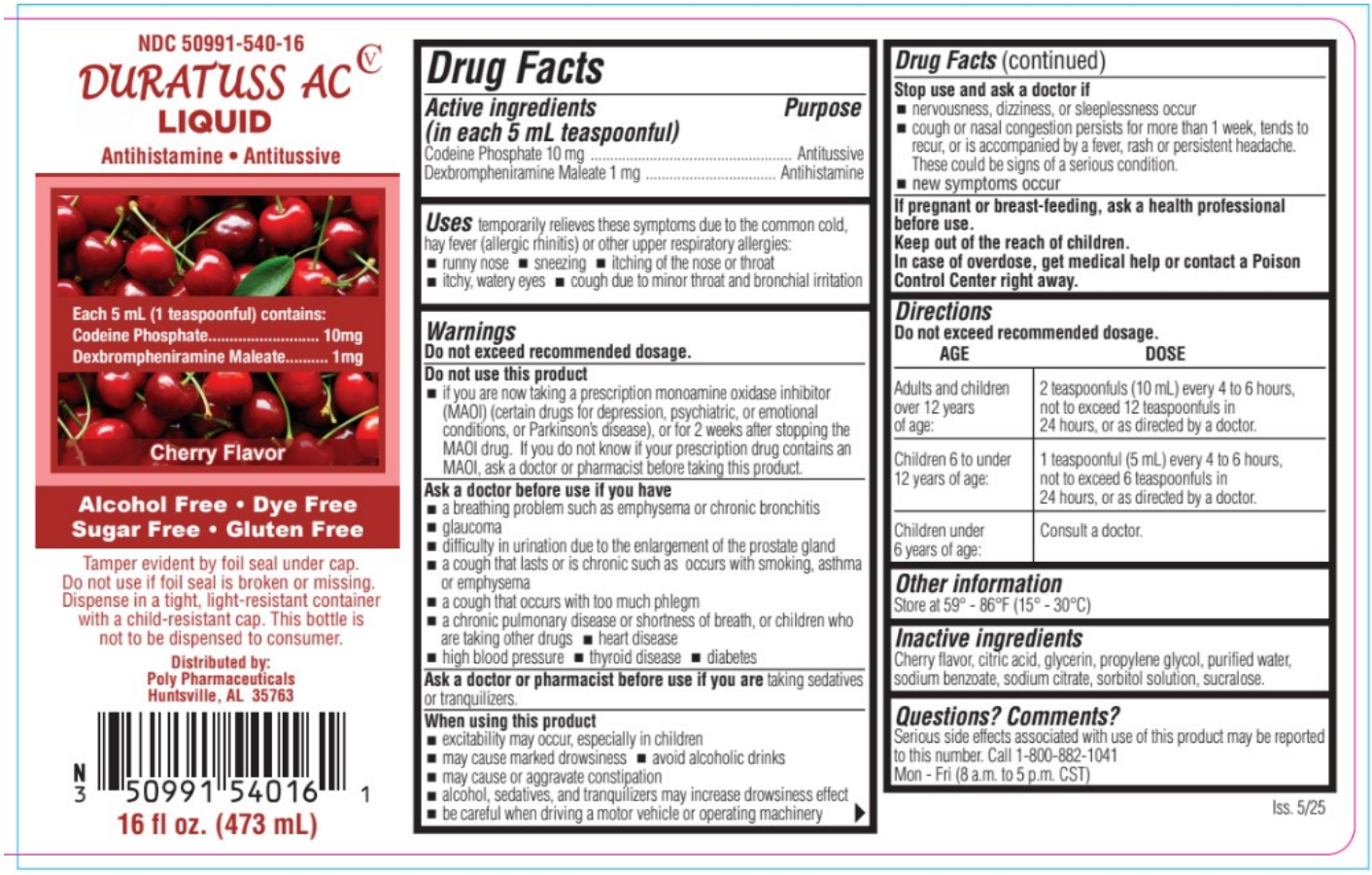
Other information

Store at room temperature 15°C-30°C (59°F-86°F)

Questions? Comments? Serious side effects associated with use of this product may be reported to this number. Call 1-800-882-1041
Mon. - Fri. (8 a.m. to 5 p.m. CST).

Inactive ingredients

Inactive ingredients Cherry flavor, citric acid, glycerin, propylene glycol, purified water,sodium benzoate, sodium citrate, sorbitol solution, sucralose.



DURATUSS AC

codeine phosphate, dexbrompheniramine maleate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50991-540
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY (dye free, sugar free)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-540-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2025	
2	NDC:50991-540-20	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/08/2025	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 9/2025 Poly Pharmaceuticals, Inc.