ACTIDOM DA- chlorpheniramine maleate, phenylephrine hydrochloride solution
Actipharma, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTIDOM® DA

Drug Facts

Active Ingredients (in each 5 mL tsp)

Chlorpheniramine Maleate, 1 mg

Phenylephrine HCL, 2.5 mg

Purposes

Antihistamine

Nasal Decongestant

Uses

• temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itching of the nose or throat
• itchy, watery eyes • nasal congestion
• temporarily restores free breathing through the nose

Warnings

Do not use in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if child has
• heart disease • diabetes • high blood pressure • thyroid disease • glaucoma • a breathing problem such as chronic bronchitis

When using this product • do not exceed recommended dosage
• excitability may occur, especially in children
• may cause drowsiness
• do not give this product to children who are taking sedatives of tranquilizers, without first consulting the child's doctor

Stop use and ask a doctor if
• nervousness, dizziness, or sleeplessness occur
• symptoms do not improve within 7 days or are accompanied by fever. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

• do not take more than 6 doses in any 24-hour period.

Children under 6 to under 12 years of age	Take 2 teaspoon (10 mL), every 4 hours
Children under 6 years of age	Consult a doctor

Other information

• Store at controlled room temperature: 15°-30°C (59°-86°F).
• Tamper Evident Feature: Do not use if inner seal is torn, broken or missing.

Inactive ingredients

Citric acid, D&C Red 33, hydroxyethyl cellulose, flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate and sucralose.

Questions or comments?

call weekdays from 8AM to 4PM AST at **1-787-608-0882**

Contains the same active ingredients as Dometuss® - DA*

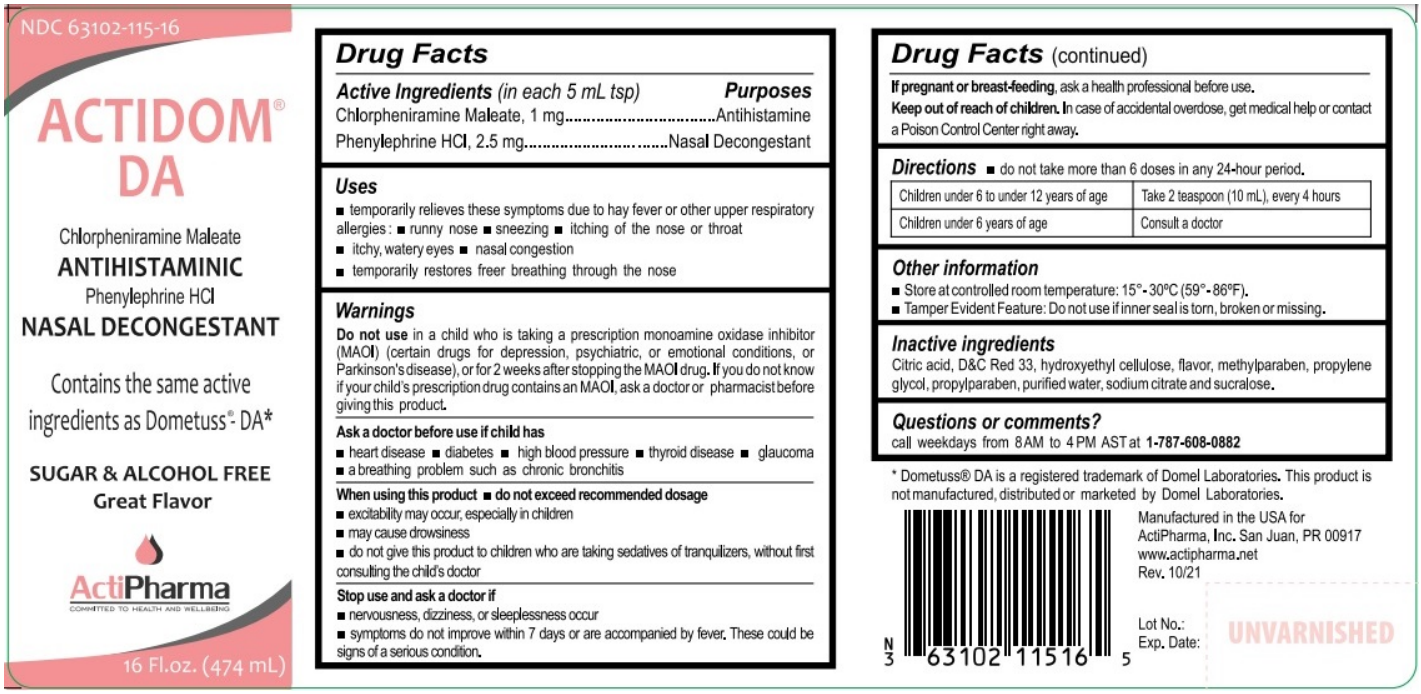
SUGAR & ALCOHOL FREE

Great Flavor

*Dometuss® DA is registered trademark of Domel Laboratories. This product is not manufactured, distributed or marketed by Domel Laboratories.

Manufactured in the USA for
ActiPharma, Inc. San Juan, PR 00917
www.actipharma.net

Packaging



ACTIDOM DA

chlorpheniramine maleate, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63102-115
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	pink (LIGHT PINK)	**Score**	
Shape		**Size**	
Flavor	BANANA, STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63102-115-16	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/20/2022	

Labeler - Actipharma, Inc (079340948)

Revised: 1/2022 Actipharma, Inc