ATUSS DA- brompheniramine maleate, chlophedianol hydrochloride, pseudoephedrine hydrochloride liquid
Magna Pharmceuticals, 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.

ATUSS DA

Drug Facts

Active ingredients

(in each 5mL teaspoonful)

Brompheniramine Maleate 2 mg

Chlophedianol Hydrochloride 12.5 mg

Pseudoephedrine Hydrochloride 30 mg

Purpose

Antihistamine

Cough Suppressant

Nasal Decongestant

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

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

Warnings

Do not exceed recommended dosage.

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 physician or pharmacist before taking this product.

Ask a physician before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis

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

When using this product
- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a physician 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.

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

Keep out of the reach of children.

In case of an accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	2 teaspoonfuls (10 mL) every 6 hours, not to exceed 8 teapoonfuls (40 mL) in 24 hours.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 6 hours, not to exceed 4 teaspoonfuls (20 mL) in 24 hours.
Children under 6 years of age:	Consult a physician

Other information

Store at 59° - 86°F (15° - 30°C)

Inactive ingredients

Citric Acid, Glycerin, Grape Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

Questions? Comments?

Call your physician for medical advice. Serious side effects associated with this product may be reported to this number. 1-888-206-5525, 8 am - 5 pm, M-F *EST*

Manufactured for:

MAGNA

Phamaceuticals, Inc.

Accountability.

Louisvill, KY 40299
magnaweb.com
Rev. 01/18

ATUSS DA 4fl oz (118 mL) Bottle Label

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Supplied in a tight, light-resistant container, as defined in the USP, with a child-resistant closure.

Manufactured for:
MAGNA Pharmaceuticals, Inc.
Accountability
Louisville, KY 40299
magnaweb.com
Rev. 01/18
US Patent # 9,050,289 B2

N 3 58407-252-04 2

NDC 58407-252-04

ATUSS DA

Each teaspoonful (5 mL) for oral administration contains:
Brompheniramine Maleate .. 2 mg
Chlophedianol HCl ..... 12.5 mg
Pseudoephedrine HCl ..... 30 mg

GRAPE FLAVORED LIQUID

- **Antihistamine**
- **Cough Suppressant**
- **Nasal Decongestant**

Sugar Free/Alcohol Free
Dye Free

4 fl. oz. (118 mL)

Drug Facts Lift Here

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Drug Facts (continued)

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MAGNA Pharmaceuticals, Inc.
Accountability
Louisville, KY 40299
magnaweb.com
Rev. 01/18

ATUSS DA
brompheniramine maleate, chlophedianol hydrochloride, pseudoephedrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58407-252
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	2 mg in 5 mL
CHLOPHEDIANOL HYDROCHLORIDE (UNII: 69QQ58998Y) (CHLOPHEDIANOL - UNII:42C50P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	12.5 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58407-252-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2018	
2	NDC:58407-252-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2018	
3	NDC:58407-252-01	6 in 1 CARTON	11/20/2018	
3		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/20/2018	

Labeler - Magna Pharmceuticals, Inc. (620988360)

Establishment

Name	Address	ID/FEI	Business Operations
Woodfield Pharmaceutical, LLC		079398730	manufacture(58407-252)