

APRODINE- pseudoephedrine hcl and tripolidine tablet, film coated
Rebel Distributors Corp

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.

Aprodine

Active ingredient(s)

Pseudoephedrine HCl 60 mg

Tripolidine HCl 2.5 mg

Purpose

Nasal decongestant

Antihistamine

Use(s)

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

runny nose

itchy, watery eyes

sneezing

itching of the nose or throat

temporarily relieves nasal congestion due to the common cold

Warnings

Do not use

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 rug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

high blood pressure

heart disease

thyroid disease

diabetes

glaucoma

a breathing problem such as emphysema or chronic bronchitis

trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

do not exceed recommended dose

excitability may occur, especially in children

drowsiness may occur

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 doctor if

nervousness, dizziness or sleeplessness occur

symptoms do not improve within 7 days or occur with a fever

If pregnant or breast-feeding,

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.

Directions

adults and children 12 years and over: take 1 tablet every 4 to 6 hours. Do not take more than 4 tablets in 24 hours.

children under 12 years: do not use this product in children under 12 years of age

Other information

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

see end flap for expiration date and lot number

Inactive ingredients

corn starch, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silica gel, stearic acid, titanium dioxide

Questions or comments?

To Report Adverse Drug Event Call: (800) 616-2471

Principal Display Panel



APRODINE

pseudoephedrine hcl and tripolidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-929(NDC:0904-0250)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8 T9 S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	44;178
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-929-60	60 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/09/1993	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 8/2011

Rebel Distributors Corp