APRODINE- pseudoephedrine hcl, triprolidine hcl tablet, film coated Major Pharmaceuticals

Major 44-287A

Active ingredients (in each tablet)

Pseudoephedrine HCl 60 mg Triprolidine HCl 2.5 mg

Purpose

Nasal decongestant Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:
 - runny nose
 - itchy, watery eyes
 - nasal congestion
 - sneezing
 - itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing
 - nasal congestion

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 drug. 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
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- use caution when driving a motor vehicle or operating machinery
- drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness

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

- do not take more than directed
- 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

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

hypromellose, magnesium stearate, polyethylene glycol, silicified microcrystalline cellulose, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

MAJOR®

NDC 0904-7302-24

Maximum Strength

Aprodine[™] Tablets Pseudoephedrine HCl 60 mg Triprolidine HCl 2.5 mg

60 mg/2.5 mg

Nasal Decongestant/Antihistamine

Relieves Nasal Congestion, Sneezing, Runny Nose, Itchy, Watery Eyes

Actual Size

24 Tablets

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

50844 ORG112328708

Distributed by: MAJOR® PHARMACEUTICALS Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.com

■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
■ see end flap for expiration date and lot number

Other information ■ Tamper evident: Do Not Use IF Outer Package IS Opened Or Blister is torn or broken

Directions

In do not take more than directed

In 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.

In children under 12 years: do not use

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.

Stop use and ask a doctor if m nervousness, dizziness, or sleeplessness occur m symptoms do not improve within 7 days or occur with fever

■ svoid slcoholic beverages
■ svoid slcoholic beverages
■ use caution when driving a motor vehicle or operating machinery
■ alcohol, sedatives, and tranquilizers may increase drowsiness

When using this product on not exceed recommended dosage drowsiness may occur

Drug Facts (continued)

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

Ask a doctor before use if you have III high blood pressure
III heart disease III thy oid disease III dispetes III glaucoma
III a breathing problem such as emphysema or chronic bronchitis
III a breathing problem such as emphysement of the prostate gland
III difficulty in urination due to enlargement of the prostate gland

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Warmings

Do not use if you are now taking a prescription monoamine oxidase
inhibitor (MAD) (certain drugs for depression, psychiatric, or
emotional conditions, or Parkinson's disease), or for 2 weeks after
alonging the MADI drug. If you do not know if your prescription drug
contains an MADI, ask a doctor or pharmacist before taking this

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 temporarily relieves these symptoms due to the common cold:
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 I runny nose itchy, watery eyes nasal congestion
- em temporarily relieves these symptoms due to hay fever (allergic

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Wasal decongestant decongestant Antihistamine

Active ingredients (in each tablet)
Perioephedine HOI 60 mg

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Triprolidine HCI 2.5 mg.

MAJOR°

Maximum Strength

Aprodine™ Tablets

Pseudoephedrine HCl 60 mg Triprolidine HCl 2.5 mg NDC 0904-7302-24

NDC 0904-7302-24

B-1212-287A-08 0RG112328708

MAJOR°

Maximum Strength

Aprodine™ Tablets

Pseudoephedrine HCl 60 mg Triprolidine HCl 2.5 mg

60 mg/2.5 mg

Nasal Decongestant/Antihistamine

Relieves Nasal Congestion, Sneezing, Runny Nose, Itchy, Watery Eyes Actual Size



24 Tablets

MAJOR° PHARMACEUTICALS (800) 616-2471
Distributed by:

0844 ORG112328708

Questions or comments? 1-800-426-9391

Inactive ingredients
hypromellose, magnesium stearate, polyethylene glycol, silicified
microcrystalline cellulose, titanium dioxide

Drug Facts (continued)

Major 44-287A

APRODINE

pseudoephedrine hcl, triprolidine hcl tablet, film coated

TAMPER EVIDENT: DO NOT U
PACKAGE IS OPENED OR IF BIL
UNIT STORN, BROKEN OR SI
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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7302
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg		
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII: 2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg		

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	287
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0904- 7302-24	1 in 1 CARTON	11/11/2022			
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:0904- 7302-60	1 in 1 CARTON	11/11/2022			
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	11/11/2022		

Labeler - Major Pharmaceuticals (191427277)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0904-7302)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-7302) , pack(0904-7302)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-7302)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-7302)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-7302)

Revised: 4/2024 Major Pharmaceuticals