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

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.

Major 44-178

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 (1-800-222-1222) 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

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

colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, stearic acid, titanium dioxide

Questions or comments?

(800) 616-2471

Principal Display Panel

MAJOR®

NDC 0904-0250-24

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 REV0719N17808

Distributed by:
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152

Rev. 11/19 M-17
Re-order No. 700796

Major 44-178

APRODINE

pseudoephedrine hcl and triprolidine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-0250
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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	44;178
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-0250-24	1 in 1 CARTON	01/09/1993	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-0250-59	1 in 1 CARTON	01/09/1993	
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 FINAL	part341	01/09/1993	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0904-0250)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0904-0250)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0904-0250)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0904-0250)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0904-0250)

Revised: 12/2020 Major Pharmaceuticals