

**APRODINE- pseudoephedrine hcl and triprolidine tablet, film coated  
Proficient Rx LP**

*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 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 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
- 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 25°C (77°F); excursions permitted between 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?***

**(800) 616-2471**

## **Principal Display Panel**

**MAJOR®**

**NDC 71205-100-24**

**Aprodine™**

**TABLETS**

**TRIPROLIDINE HCl AND PSEUDOEPHEDRINE HCl  
DECONGESTANT/ANTIHISTAMINE/FILM COATED**

## Head Cold & Allergy Medicine

### Relieves:

- Nasal Congestion • Runny Nose
- Sneezing • Itchy, Watery Eyes

24 TABLETS

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

50844 REV0612M17808

Distributed by

**MAJOR® PHARMACEUTICALS**

31778 Enterprise Drive

Livonia, MI 48150 USA M-17

Relabeled by

**Proficient Rx LP**

Thousand Oaks, CA 91320

Re-Order No. 700796

Rev. 09/13



NDC 71205-100-24

Lot #:00000  
Exp. 00/00/00  
SN# MASTER

Aprodine 60mg / 2.5mg  
#24 Tablets  
Lot #:00000 SN#MASTER  
NDC 71205-100-24 Exp.00/00/00

Aprodine 60mg / 2.5mg  
#24 Tablets  
Lot #:00000 SN#MASTER  
NDC 71205-100-24 Exp.00/00/00

Aprodine 60mg / 2.5mg  
#24 Tablets  
Lot #:00000 SN#MASTER  
NDC 71205-100-24 Exp.00/00/00

**Aprodine 60mg / 2.5mg**  
**#24 Tablets**

Each film coated tablet contains: Pseudoephedrine HCL 60mg Nasal Decongestant / Triprolidine HCL 2.5mg Antihistamine.  
*White, round, scored tablet with imprint code "44" and "178".*

Product ID: SA010024

Dist. By: Major Pharmaceuticals 31778 Enterprise Drive, Livonia, MI 48150 USA  
Store at 25°C (77°F) Keep medication out of the reach of children

Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

## APRODINE

pseudoephedrine hcl and triprolidine tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71205-100(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)				
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)				
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:71205-100-24	1 in 1 CARTON	09/04/2018	
1		24 in 1 BLISTER PACK; 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** - Proficient Rx LP (079196022)

Establishment			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-100)