APRODINE- pseudoephedrine hcl, triprolidine hcl tablet, film coated A-S Medication Solutions

APRODINE

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, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide

Questions or comments?

1-800-426-9391

HOW SUPPLIED

Product: 50090-7085

Pseudoephedrine HCI, Triprolidine HCI



APRODINE

pseudoephedrine hcl, triprolidine hcl tablet, film coated

| Product | Inform | ation |
|---------|--------|-------|
| riouuct | | ation |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50090-7085(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) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| Color | white | Score | no score |
|----------|-------|--------------|----------|
| Shape | ROUND | Size | 7mm |
| Flavor | | Imprint Code | 287 |
| Contains | | | |

| Packaging | | | |
|---------------------------|---|-------------------------|-----------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:50090-7085-2 | 1 in 1 CARTON | 02/05/2024 | |
| 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 Drug | M012 | 11/11/2022 | |
| | | | |

Labeler - A-S Medication Solutions (830016429)

| Establishment | | | |
|--------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| A-S Medication Solutions | | 830016429 | RELABEL(50090-7085) |

Revised: 2/2024 A-S Medication Solutions