SCOT-TUSSIN ORIGINAL MULTI-SYMPTOM COLD AND ALLERGY RELIEF- acetominophen, phenylephrine hydrochloride and pheniramine maleate liquid
IriSys, LLC

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.

Scot-Tussin Original Multi-Symptom Cold and Allergy Relief

Drug Facts

Active ingredient (in each 5 mL tsp. teaspoon)

Acetaminophen USP 160 mg

Purpose

Pain reliever/Fever reducer

Active ingredient (in each 5 mL tsp. teaspoon)

Pheniramine Maleate USP 4 mg

Purpose

Antihistamine

Active ingredient (in each 5 mL tsp. teaspoon)

Phenylephrine HCI USP 4 mg

Purpose

Decongestant

Uses

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains.
  - headaches.
  - minor sore throat.
  - nasal congestion.
  - temporarily reduces fever.

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose.
  - sneezing.
  - itchy nose and throat.
  - itchy, watery eyes.

Warnings

DO NOT USE THIS PRODUCT TO SEDATE CHILDREN

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 doses in 24 hours, which is the maximum daily amount.
- with other drugs containing acetaminophen.
- 3 or more alcoholic drinks every day while using this product.

Do not use:

- with any other drug containing acetaminophen (prescription or nonprescription). if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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

- liver disease.
- heart disease.
- high blood pressure.
- thyroid disease.
- diabetes.
- glaucoma.
- a breathing problem such as emphysema, asthma 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.
- taking the blood thinning drug warfarin.

When using this product

- **do not use more than directed.**
- avoid alcoholic drinks.
- drowsiness may occur.
- alcohol, sedatives and tranquilizers may increase drowsiness.
- be careful when driving a motor vehicle or operating machinery.
- excitability may occur, especially in children.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless.
- pain or nasal congestion gets worse or lasts more than 7 days.
- fever gets worse or lasts more than 3 days.
- redness or swelling is present.
- new symptoms occur.
- sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting.

If pregnant or breast-feeding,

Do Not Use.

Keep out of reach of children.

In case of overdose get medical help or contact a Poison Control Center right away. Quick medical

attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed – see Liver warning.
- follow Dosage Chart.
- do not take more than 4 doses in any 24 hour period.
- this product is not intended for use in children under 12 years of age.

age	dose
Adults and children over 12 years old	2 teaspoons (2 tsp. 10 mL) every 6 hours
Children under 12 years old	DO NOT USE

Other information

- each teaspoon (5 mL) contains: Potassium 17.5 mg.
- store at 20°- 25° C (68°-77°F).
- do not refrigerate.
- dosage cup provided

Inactive ingredients

ammonium glycyrrhizate, citric acid, clear cherry-strawberry flavor, glycerin, hydroxyethylcelluose, methyl-paraben, polyethylene glycol, potassium benzoate, potassium citrate, propyl-paraben, purified water, sucralose.

Distributed by:
IriSys, LLC
San Diego, CA 92121 U.S.A.
Questions? 1-800-638-7268
www.scot-tussin.com
®TM Reg. US Patent Office No. 657, 674

PRINCIPAL DISPLAY PANEL

SUGAR-FREE
ADULT
NDC 15187-004-04
For Diabetics since 1956
SCOT-TUSSIN®
ORIGINAL
MULTI-SYMPTOM
COLD & ALLERGY RELIEF
ACETAMINOPHEN (pain reliever, fever reducer)
PHENIRAMINE MALEATE (antihistamine)
PHENYLEPHRINE HCI (nasal decongestant)

FAST RELIEF OF:
PAIN, FEVER, STUFFY HEAD,
SINUS CONGESTION, ITCHY,
RUNNY NOSE

- FIRST SUGAR & ALCOHOL-FREE

- LACTOSE & GLUTEN-FREE
- SODIUM-FREE
- DYE-FREE

LIQUID
4 FL OZ (118 ml)

SCOT-TUSSIN ORIGINAL MULTI-SYMPTOM COLD AND ALLERGY RELIEF

acetominophen, phenylephrine hydrochloride and pheniramine maleate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:15187-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	4 mg in 5 mL
PHENIRAMINE MALEATE (UNII: NYW905655B) (PHENIRAMINE - UNII:134FM9ZZ6M)	PHENIRAMINE MALEATE	4 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POTASSIUM BENZOATE (UNII: 763YQN2K7K)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY (clear cherry-strawberry flavor) , STRAWBERRY (clear cherry-strawberry flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15187-004-04	1 in 1 CARTON		
1		118 mL in 1 BOTTLE; 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	01/01/2016	

Labeler - IriSys, LLC (079682716)

Revised: 10/2015 IriSys, LLC