

**THERAFLU COLD AND FLU- acetaminophen, pheniramine maleate,
phenylephrine hydrochloride powder
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

Drug Facts

TheraFlu Cold and Flu

Pharmaceutical form: Powder for oral solution (berry flavor).

Active Ingrédients

paracetamol 325.0 mg

pheniramine maleate 20.0 mg

phenylephrine hydrochloride 10.0 mg.

Purpose

Antipyretic
Analgesic
Vasoconstrictive
Decongestant
Antiallergic

Indications:

Symptomatic therapy of infectious and inflammatory disorders: acute respiratory viral infections (ARVI) including influenza and common cold associated with: high temperature, chill, headache, sore throat, rhinitis, nasal congestion, sneezing, muscle pain.

Dosage and administration:

For oral administration. Dissolve one sachet in a glass of hot, but not boiling, water. Take hot.

Take one sachet every 4 – 6 hours as required but not more than 4 doses within 24 hours. The product should not be administered for more than 5 days.

Excipients: see patient information leaflet

Contraindications:

Hypersensitivity to individual product ingredients, co-administration of tricyclic antidepressants, beta-adrenergic blockers or other sympathomimetic products, hyperthyroidism, pheochromocytoma, angle-closure glaucoma, alcoholism, pregnancy,

breastfeeding, pediatric use under 12 years of age. For a complete list of contraindications, see patient information leaflet.

Excipients:

sucrose, acesulfame potassium, Allura Red AC E129 (FD&C red No.40), Brilliant Blue E133 (FD&C No.1), maltodextrin, silicon dioxide, natural raspberry flavor WONF Durarome (860385 TD0994), natural cranberry Durarome flavor (861149 TD2590, citric acid anhydrous, sodium citrate dihydrate, calcium phosphate tribasic, magnesium stearate.

Storage conditions:

At temperature not higher than 25°C.

Keep out of reach of children.

OTC medicine

Marketing authorisation No. JC-001960

Principal Display Panel

NDC 0067-0924-01

THERAFLU

COLD & FLU

contains paracetamol 325 mg

**FEVER MUSCLE PAIN
HEADACHE RUNNYNOSE
SORE THROAT NASAL CONGESTION
CHILLS SNEEZING**

Berry flavour

10 SACHETS



THERAFLU COLD AND FLU

acetaminophen, pheniramine maleate, phenylephrine hydrochloride powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-0924
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENIRAMINE MALEATE (UNII: NYW905655B) (PHENIRAMINE - UNII:134FM9Z26M)	PHENIRAMINE MALEATE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0924-01	10 in 1 CARTON; Type 0: Not a Combination Product	03/01/2022	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only			03/01/2022	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)