THERAFLU SEVERE COLD RELIEF DAYTIME HONEY GINGER- acetaminophen, dextromethorphan hbr powder, for solution Haleon US Holdings LLC

Drug Facts

Active ingredients (in each packet)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Purposes

Pain reliever/Fever reducer

Cough suppressant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning:If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly.

Do not use

• in a child under 12 years of age

- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a 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 doctor before use if you have

- liver disease
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

• taking the blood thinning drug warfarin

Stop use and ask a doctor if

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts These could be signs of a serious condition.

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

Directions

- do not use more than directed
- take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

 dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes. • if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Other information

- each packet contains:potassium 5 mg, sodium 21 mg
- phenylketonurics:contains phenylalanine 14 mg per packet
- store at controlled room temperature 20 °-25 °C (68 °- 77 °F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no.10, FD&C blue no. 1, FD&C red no. 40, maltodextrin, natural and artificial flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

Ouestions or comments?

1-855-328-5259

Additional information

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.

KEEP CARTON FOR REFERENCE, DO NOT DISCARD.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

TAMPER EVIDENT INNER UNIT

DO NOT USE IF SEALED THERAFLU PACKET IS TORN OR BROKEN

1-855-328-5259

Distributed by: Haleon, Warren, NJ 07059

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Pat. Info www.productpats.com

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Principal Display
NEW FORMULA
HALEON
THERAFLU

SEVERE COLD RELIEF

Acetaminophen - Pain Reliever/Fever Reducer

Dextromethorphan HBr - Cough Suppressant

DAYTIME FORMULA

Hot liquid therapy that relieves:

1. / Cough

/ Sore throat pain

/ Head and body ache

/ Fever

Honey Ginger Flavor

6 PACKETS



THERAFLU SEVERE COLD RELIEF DAYTIME HONEY GINGER

acetaminophen, dextromethorphan hbr powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-0103
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name
Basis of Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)
ACETAMINOPHEN
650 mg

TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)

DEXTROMETHORPHAN HYDROBROMIDE

20 mg

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
ASPARTAME (UNII: Z0H242BBR1)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
SUCROSE (UNII: C151H8M554)		

Product Characteristics			
Color	yellow (white to off-white, beige, and brown)	Score	
Shape		Size	
Flavor	HONEY (Ginger)	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0103- 06	6 in 1 CARTON	12/01/2023	
1		1 in 1 PACKET; 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	12/01/2023	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC