

**THERAFLU SEVERE COLD RELIEF DAYTIME WITH HONEY GINGER FLAVOR-
acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for
solution
Haleon US Holdings LLC**

Drug Facts

Active ingredients (in each packet)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/Fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
 - minor aches and pains
 - minor sore throat pain
 - headache
 - nasal and sinus congestion
 - 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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

When using this product

- **do not exceed recommended dosage**

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs

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, aspartame, citric acid, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, honey solids, maltodextrin, medium chain triglycerides, natural flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, triacetin, tribasic calcium phosphate

Questions 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

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Principal Display Panel

THERAFLU

NEW FLAVOR

MULTI-SYMP TOM COLD RELIEF

SEVERECOLD RELIEF

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

DAYTIME FORMULA

Hot liquid therapy

that relieves:

/ Nasal and sinus congestion

/ Cough

/ Sore throat pain

/ Headache

/ Fever

Honey Ginger

6 PACKETS

PA 62000000200567 – Carton Front



THERAFLU SEVERE COLD RELIEF DAYTIME WITH HONEY GINGER FLAVOR

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-8211
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1VS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HONEY (UNII: Y9H1V576FH)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TRACETIN (UNII: XHX3C3X673)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	white (off-white, beige, brown)	Score	
Shape		Size	
Flavor	HONEY (Ginger)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8211-01	6 in 1 CARTON	05/01/2023	
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	05/01/2023	

Labeler - Haleon US Holdings LLC (079944263)