

**THERAFLU SEVERE COLD RELIEF SOFT CHEWS- acetaminophen,
dextromethorphan hbr tablet, chewable
Haleon US Holdings LLC**

Drug Facts

Active ingredients (in each chewable tablet)

Acetaminophen 325 mg

Dextromethorphan equivalent to 10 mg Dextromethorphan HBr

Purposes

Pain reliever/Fever reducer

Cough suppressant

Uses

- temporarily relieves these symptoms due to a cold:
 - minor aches and pains
 - 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 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
- 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 or cough 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**
- do not take more than 10 chewable tablets in 24 hours unless directed by a doctor. Take every 4 hours, while symptoms persist.

Age	Dose
adults and children 12 years of age and over	take 2 chewable tablets every 4 hours
children under 12 years of age	do not use

Other information

- **each chewable tablet contains:** potassium 10 mg, sodium 6 mg
- store at a controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

calcium gluconate monohydrate, carboxymethylcellulose calcium, carnauba wax, corn syrup solids, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, glycerin, mannitol, natural and artificial flavors, pregelatinized starch, simethicone, sodium gluconate, sorbitol, sorbitol solution, sucralose, sucrose, whole dry milk

Questions or comments?

call **1-855-328-5359**

Generic Section

Do Not Use if seal under bottle cap imprinted with "*SEALED for YOUR PROTECTION*" is broken or missing.

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Package/Label Principal Display Panel

NEW

THERAFLU

SEVERE COLD RELIEF

SOFT CHEWS

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

FAST relief ANYWHERE

cough / sore throat / headache / body aches / fever

20 CHEWABLE TABLETS

Chew tablets completely before swallowing

Apple Cinnamon Flavor

NEW HALÉON

THERAFLU

SEVERE COLD RELIEF

Soft CHEWS

Acetaminophen
Pain Reliever/Fever Reducer
Dextromethorphan HBr
Cough Suppressant

FAST relief ANYWHERE
cough / sore throat
/ headache / body aches
/ fever

20 CHEWABLE TABLETS
Chew tablets completely before swallowing

Apple
Cinnamon
Flavor

THERAFLU SEVERE COLD RELIEF SOFT CHEWS

acetaminophen, dextromethorphan hbr tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-0111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM GLUCONATE MONOHYDRATE (UNII: CZN0MI5R31)	
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CORN SYRUP (UNII: 9G5L16BK6N)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SORBITOL (UNII: 506T60A25R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
COW MILK (UNII: 917J3173FT)	

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	21mm
Flavor	APPLE, CINNAMON	Imprint Code	T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0111-01	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2024	
2	NDC:0067-0111-02	10 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/19/2024	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 6/2024

Haleon US Holdings LLC