

**THERAFLU SEVERE COLD RELIEF NIGHTTIME SOFT CHEWS- acetaminophen,
diphenhydramine hcl tablet, chewable
Haleon US Holdings LLC**

Drug Facts

Active ingredients (in each chewable tablet)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Purposes

Pain reliever/Fever reducer

Antihistamine/Cough suppressant

Uses

- temporarily relieves these symptoms due to a cold:
 - minor aches and pains
 - sore throat pain
 - headache
 - runny nose
 - sneezing
 - itchy nose or throat
 - itchy, watery eyes due to hay fever
 - 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.
- with any other product containing diphenhydramine, even one used on the skin

Ask a doctor before use if you have

- liver disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- 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 sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- avoid alcoholic drinks
- marked 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

- 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:** calcium 10 mg, potassium 10 mg, sodium, 7 mg
- store at a controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

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

Questions or comments?

call **1-855-328-5259**

Generic Section

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

Package/Label Principal Display Panel

NEW

THERAFLU

SEVERE COLD RELIEF

NIGHTTIME

Soft CHEWS

Acetaminophen

Pain Reliever/Fever Reducer

Diphenhydramine HCl

Antihistamine/Cough Suppressant

FASTrelief ANYWHERE

fever / cough / headache / body aches / sore throat / runny nose / sneezing / watery eyes

20 CHEWABLE TABLETS

Chew tablets completely before swallowing

Apple Cinnamon Flavor



THERAFLU SEVERE COLD RELIEF NIGHTTIME SOFT CHEWS

acetaminophen, diphenhydramine hcl tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-0112
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg		
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg		
Inactive Ingredients				
Ingredient Name		Strength		
BROWN IRON OXIDE (UNII: 1N032N7MFO)				
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)				
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	N	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0112-01	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	09/30/2024		

Labeler - Haleon US Holdings LLC (079944263)