

**ALKA-SELTZER PLUS COUGH AND SORE THROAT FIZZYCHEWS-
acetaminophen, dextromethorphan hydrobromide tablet, chewable
Bayer HealthCare LLC.**

Alka-Seltzer Plus Cough and Sore Throat FizzyChews UI 1615059

Drug Facts

Active ingredients (in each tablet) Purposes

Acetaminophen 162.5 mg.....Pain reliever/fever reducer

Dextromethorphan hydrobromide 5 mg.....Cough suppressant

Uses

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

Warnings

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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

- skin reddening · blisters · rash · hives
- facial swelling · asthma (wheezing) · shock

If a skin or general allergic 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

- 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.

- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 6 years of age

Ask a doctor before use if you have

- liver disease
- cough with excessive phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a sodium restricted diet

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

When using this product

- **do not exceed recommended dosage**
- may cause marked drowsiness
- avoid alcoholic drinks
- 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

- pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

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

Directions

Directions

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 tablets every 4 hours.

Do not exceed 6 doses (12 tablets) tablets in 24 hours or as directed by a

doctor.

- children 6 to under 12 years: take 2 tablets every 4 hours. Do not exceed 5 doses (10 tablets) in 24 hours or as directed by a doctor.
- do not swallow tablets whole. Chew or crush tablets completely before swallowing.
- children under 12 years: do not use

Other information

- **each tablet contains:** sodium 17 mg
- store at room temperature. Avoid excessive heat above 40 ° C (104 ° F)

Inactive ingredients anhydrous citric acid, betadex, carboxymethylcellulose, colloidal silicon dioxide, ethylcellulose, flavors, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene, sodium bicarbonate, sodium carbonate, sodium starch glycolate, stearic acid, sucralose, xylitol

Questions or comments

Questions or comments? 1-800-986-0369 (Mon-Fri 9AM - 5PM EST)

Alka-Seltzer® PLUS

Cough & Sore Throat FIZZY **CHEWS**

ACETAMINOPHEN/Pain Reliever-Fever Reducer

Dextromethorphan HBr/ Cough Suppressant

- Fever & Body Ache
- Cough
- Sore Throat

ACTIVATES WITHOUT WATER

24 CHEWABLE TABLETS



ALKA-SELTZER PLUS COUGH AND SORE THROAT FIZZYCHEWS

acetaminophen, dextromethorphan hydrobromide tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0152
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	162.5 mg

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z 65AP)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MANNITOL (UNII: 3OWL53L36A)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SUCRALOSE (UNII: 96K6UQ3Z D4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	
XYLITOL (UNII: VCQ006KQ1E)	

BETADEX (UNII: JV039JZZ3A)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	17mm
Flavor		Imprint Code	ASP;13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0152-01	2 in 1 CARTON	04/01/2024	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0280-0152-02	3 in 1 CARTON	04/01/2024	
2		8 in 1 BLISTER PACK; 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	04/01/2024	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 3/2024

Bayer HealthCare LLC.