ALKA-SELTZER PLUS COLD AND FLU FIZZYCHEWS- chlorpheniramine maleate, acetaminophen, dextromethorphan hydrobromide tablet, chewable
Bayer HealthCare LLC.

Alka-Seltzer Plus Cold & Flu FizzyChews UI 1615333

Drug Facts

Active ingredients (in each tablet) Purposes

Acetaminophen 162.5 mg……Pain reliever/fever reducer

Chlorpheniramine maleate 2 mg……Antihistamine

Dextromethorphan hydrobromide 5 mg……Cough suppressant

Uses

· temporarily relieves these symptoms due to a cold or flu:

· minor aches and pains · headache · cough

· runny nose · sneezing · sore throat

· 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 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 to sedate children

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 12 years of age

Ask a doctor before use if you have

● liver disease ● glaucoma

● cough with excessive phlegm (mucus)

● a breathing problem such as emphysema or chronic bronchitis

● difficulty in urination due to enlargement of the prostate gland

● persistent or chronic cough such as occurs with smoking, asthma, or emphysema

● a sodium restricted diet

Ask a doctor or pharmacist before use if you are

● taking the blood thinning drug warfarin

● taking sedatives or tranquilizers

When using this product

● marked drowsiness may occur

● avoid alcoholic drinks

● excitability may occur, especially in children

● alcohol, sedatives, and tranquilizers may increase drowsiness

● be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

· pain, cough, or nasal congestion gets worse or lasts more than 7 days

· 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. 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. 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 12 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 ºC

(104 ºF)

Inactive ingredients anhydrous citric acid, betadex,

carboxymethylcellulose, colloidal silicon dioxide, ethylcellulose, flavors,

magnesium searate, 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

Orange Flavor

Cold

& Flu

FIZZY **CHEWS**

ACETAMINOPHEN/Pain Reliever-Fever Reducer

Chlorpheniramine Maleate/Antihistamine

Dextromethorphan HBr/ Cough Supressant

Phenylephrine Hydrochloride/Nasal Decongestant

- Cough
- Runny Nose
- Sneezing
- Fever & Body Ache
- Sore Throat

ACTIVATES

WITHOUT

WATER

24 CHEWABLE TABLETS

ALKA-SELTZER PLUS COLD AND FLU FIZZYCHEWS

chlorpheniramine maleate, acetaminophen, dextromethorphan hydrobromide tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-0151
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	162.5 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
XYLITOL (UNII: VCQ006KQ1E)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
BETADEX (UNII: JV039JZZ3A)	
MICROCRYSTALLINE CELLULOSE 102 SCG (UNII: HHJ82DN6MJ)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	17mm
Flavor		**Imprint Code**	ASP;11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0151-01	3 in 1 CARTON	04/01/2024	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0280-0151-02	2 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)