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

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**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) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MANNITOL** (UNII: 3OWL53L36A) | |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |
| **BETADEX** (UNII: JV039JZZ3A) | |
| **MICROCRYSTALLINE CELLULOSE 102 SCG** (UNII: HHJ82DN6MJ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |

## 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)