

**ALKA-SELTZER PLUS COLD DAY AND NIGHT POWERMAX GELS-
acetaminophen, dextromethorphan hydrobromide, phenylephrine bitartrate,
doxylamine succinate
Bayer HealthCare LLC.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

**Alka-Seltzer Plus Max Strength Sinus congestion & Pain Day & Night
PowerMax gels**

Alka-Seltzer Plus® Maximum Strength Sinus Congestion & Pain Day PowerMax® Gels

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan hydrobromide 10 mg.....Cough suppressant
Phenylephrine hydrochloride 5 mg.....Nasal decongestant

Uses

temporarily relieves these symptoms due to a cold or flu:

- minor aches and pains · headache · cough
- sore throat · nasal congestion
- sinus congestion and pressure
- 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

- 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

liver disease ● heart disease ● high blood pressure

● thyroid disease ● diabetes

● cough that occurs with excessive phlegm (mucus)

● difficulty in urination due to enlargement of the prostate gland

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

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dosage

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.
- nervousness, dizziness, or sleeplessness occurs

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.

Directions

Directions

do not take more than the recommended dose

· do not take the Day and Night products at the same time; wait 4 hours after the last Night dose before starting Day product.

· adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 6 capsules in 12 hours or as directed by a doctor.

· children under 12 years: do not use

Other information

● store at room temperature. Avoid temperatures above 40°C (104°F).

SPL

FD&C yellow #6, ferric oxide, gelatin, glycerin, polyethylene glycol, potassium aluminum silicate, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

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

Package Display Label



Alka-Seltzer

PLUS®

Maximum Strength Sinus Congestion & Pain Day & Night PowerMax Gels

ALKA-SELTZER PLUS COLD DAY AND NIGHT POWERMAX GELS

acetaminophen, dextromethorphan hydrobromide, phenylephrine bitartrate, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0098
---------------------	----------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0098-01	1 in 1 CARTON; Type 0: Not a Combination Product	09/14/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 CAPSULE	16
Part 2	2 CAPSULE	8

Part 1 of 2

ALKA-SELTZER PLUS MAXIMUM STRENGTH SINUS, CONGESTION AND PAIN POWER MAX GELS

acetaminophen, dextromethorphan hydrobromide , phenylephrine hydrochloride capsule, liquid filled

Product Information

Item Code (Source)	NDC:0280-0095
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SORBITOL (UNII: 506T60A25R)	
SHELLAC (UNII: 46N107B71O)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	ASP;CC
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 BLISTER PACK		
1		8 in 1 CAPSULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2021	

Part 2 of 2

ALKA SELTZER PLUS MAXIMUM STRENGTH SINUS, ALLERGY AND COUGH POWER MAX GELS

acetaminophen, dextromethorphan hydrobromide , doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

Item Code (Source)	NDC:0280-0097
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SHELLAC (UNII: 46N107B71O)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	
SORBITAN (UNII: 6O92ICV9RU)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL (Elliptical)	Size	17mm
Flavor		Imprint Code	ASP;N
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 BLISTER PACK		
1		4 in 1 CAPSULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2018	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 6/2022

Bayer HealthCare LLC.