ALKA-SELTZER PLUS MULTI-SYMPTOM COLD AND FLU DAY AND NIGHT LIQUID GELS- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
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 Multi-Symptom Cold & Flu Day and Night Liquid Gels

Alka Seltzer Plus Multi Symptom Cold and Flu Day Liquigels

Drug Facts

Active Ingredients

Active ingredients

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Purpose

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal Decongestant

Uses

Uses

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

· minor aches and pains · headache · cough

· sore throat · nasal and sinus congestion

· temporarily reduces fever

Warnings

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

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

Ask a doctor before use if you have

● liver disease ● heart disease ● high blood pressure
● thyroid disease ● diabetes
● cough 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

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

When using this product

When using this product do not exceed recommended dosage

Stop use and ask a doctor

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

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 capsules with water

every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

· children under 12 years: do not use

Other information

Other information

· store at room temperature. Avoid excessive heat above 40ºC (104ºF).

Inactive Ingredients

Inactive ingredients

ferrosoferric oxide NF, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac purified, sorbitol-sorbitan solution

Questions or comments?

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

Alka-Seltzer Plus® Multi-Symptom Cold & Flu Night Liquid Gels

Drug Facts

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

Uses

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

· minor aches and pains · headache

· nasal and sinus congestion · cough

· sore throat · runny nose · sneezing

· 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 ● heart disease ● high blood pressure

● thyroid disease ● diabetes ● 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

Ask a doctor or pharmacist before use if you are

● taking the blood thinning drug warfarin

● taking sedatives or tranquilizers

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, 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. 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 capsules with water

every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

· children under 12 years: do not use

Other information

Other information
· store at room temperature. Avoid excessive heat above 40ºC

(104ºF).

Inactive ingredients acacia gum, ascorbic acid, citric acid,

Dl-alpha-tocopherol, ferrosoferric oxide NF, gelatin, glycerin, maltodextrin, medium chain triglyceride oil, natural beta-carotene, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol-sorbitan solution, sunflower oil

Questions or Comments

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

ALKA-SELTZER PLUS MULTI-SYMPTOM COLD AND FLU DAY AND NIGHT LIQUID GELS

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-1138

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0280-1138-20	1 in 1 CARTON; Type 0: Not a Combination Product	07/15/2016	04/19/2019

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	10
Part 2	1 BLISTER PACK	10

Part 1 of 2

ALKA-SELTZER PLUS MULTI-SYMPTOM COLD AND FLU DAY LIQUID GELS

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	white (Clear)	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	FR;DC
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1		10 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 not final	part343	07/01/2016	04/30/2019

Part 2 of 2

ALKA-SELTZER PLUS MULTI-SMPTOM COLD AND FLU NIGHT

acetaminophen, dextromethorphan hbr, doxylamine sucinate, phenylephrine hcl capsule, liquid filled

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GLYCERIN (UNII: PDC6A3C0OX)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	yellow (Light golden yellow)	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	FR;NC
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

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OTC monograph not final	part343	07/01/2016	04/30/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	07/15/2016	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 1/2023 Bayer HealthCare LLC.