ALKA-SELTZER PLUS MAXIMUM STRENGTH DAY AND NIGHT COLD AND FLUdextromethorphan hydrobromide, acetaminophen, phenylephrine hydrochloride, 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 Maximum Strength Day and Light Cold and Flu Liquid gels (project Fortify)

Drug Facts

Alka-Seltzer Plus

Maximum Strength Day & Night Cold & Flu Liquid Gels

Active ingredients (in each capsule) Purposes

Acetaminophen 325 mg......Pain reliever/fever reducer

Dextromethorphan hydrobromide 10 mg.....Cough suppressant

Phenylephrine hydrochloride 5 mg......Nasal decongestant

Uses

- \cdot temporarily relieves these symptoms due to a cold or flu:
- \cdot minor aches and pains \cdot headache \cdot cough
- \cdot sore throat \cdot nasal and sinus congestion
- \cdot temporarily reduces fever

Warnings

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

- \cdot more than 4,000 mg of acetaminophen in 24 hours
- \cdot with other drugs containing acetaminophen
- \cdot 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:

- \cdot skin reddening \cdot blisters \cdot rash \cdot hives
- \cdot facial swelling \cdot asthma (wheezing) \cdot 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 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

When using this product do not exceed recommended dosage. Stop use and ask a doctor if

 \cdot pain, cough, or nasal congestion gets worse or lasts more than

7 days

- · fever gets worse or lasts more than 3 days
- \cdot redness or swelling is present
- · new symptoms occur
- \cdot cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

 \cdot 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

 \cdot do not take more than the recommended dose

 \cdot 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.

 \cdot children under 12 years: do not use

Other information

store at room temperature. Avoid excessive heat above 40°C

(104°F).

Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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

Alka-Seltzer Plus ® Maximum Strength Night Cold & Flu Liquid Gels

Active ingredients (in each capsule) Purposes

Acetaminophen 325 mg.....Pain reliever/fever reducer Dextromethorphan hydrobromide 10 mg.....Cough suppressant Doxylamine succinate 6.25 mg.....Antihistamine Phenylephrine hydrochloride 5 mg.....Nasal decongestant

Uses

- \cdot temporarily relieves these symptoms due to a cold or flu:
- \cdot minor aches and pains \cdot headache
- \cdot nasal and sinus congestion \cdot cough \cdot sore throat
- \cdot runny nose \cdot sneezing
- · temporarily reduces fever

Warnings

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

- \cdot more than 4,000 mg of acetaminophen in 24 hours
- \cdot with other drugs containing acetaminophen
- \cdot 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:

 \cdot skin reddening \cdot blisters \cdot rash \cdot hives

 \cdot facial swelling \cdot asthma (wheezing) \cdot 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

Stop use and ask a doctor if

- \cdot pain, cough, or nasal congestion gets worse or lasts more than
- 7 days
- \cdot fever gets worse or lasts more than 3 days

- · redness or swelling is present
- · new symptoms occur
- \cdot 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

 \cdot 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 40°C

(104°F).

Inactive ingredients D&C yellow #10, FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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

Alka-Seltzer Plus®

DAY NON-DROWSY

ACETAMINOPHEN / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppresant

Phenylephrine HCI / Nasal Decongestant

- Nasal Congestion
- Headache & Body Ache
- Cough
- Sore Throat
- Sinus Congestion

12 LIQUID GELS

(LIQUID-FILLED CAPSULES)

Night

ACETAMINOPHEN / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppresant

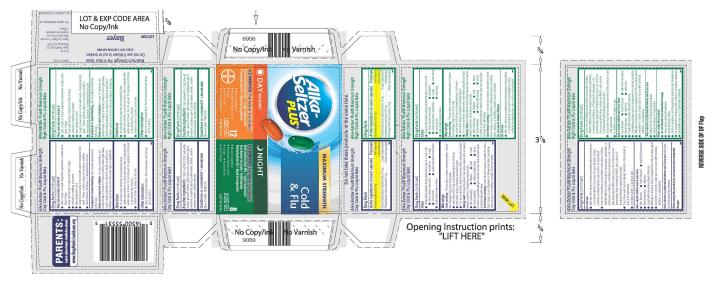
Doxylamine Succinate / Antihistamine

Phenylephrine HCl / Nasal Decongestant

- Nasal Congestion
- Headache & Body Ache
- Cough
- Runny Nose
- Sore Throat

8 LIQUID GELS

(LIQUID FILLED CAPSULES)



ALKA-SELTZER PLUS MAXIMUM STRENGTH DAY AND NIGHT COLD AND FLU

dextromethorphan hydrobromide, acetaminophen, phenylephrine hydrochloride, doxylamine succinate kit

| Product Information | | | | | | | | |
|---------------------|----------------------|--|----------|-------------------------|-----------------------|--|--|--|
| P | roduct Type | HUMAN OTC DRUG | ltem Cod | e (Source) | NDC:0280-0040 | | | |
| | | | | | | | | |
| Packaging | | | | | | | | |
| # | ltem Code | Package Descriptio | n | Marketing Start Date | Marketing End Date | | | |
| 1 | NDC:0280-0040- 01 | 1 in 1 CARTON; Type 0: Not a Comb Product | oination | 10/26/2020 | | | | |

| Quant | tity of Parts | | | | | | | | | | |
|---|---|--|-----------------------|--|-----------|--|--|--|--|--|--|
| Part # | Packag | e Quantity | Tot | tal Product Quantity | | | | | | | |
| Part 1 | | | | | | | | | | | |
| Part 2 0 BLISTER PACK 1 | | | | | | | | | | | |
| | | | | | | | | | | | |
| Part | 1 of 2 | | | | | | | | | | |
| | - | | | DAY COLD AND ne hydrochloride capsu | - | | | | | | |
| Produ | ict Information | | | | | | | | | | |
| Route | of Administration | ORAL | | | | | | | | | |
| Active | e Ingredient/Acti | - | | Pacie of Strength | Strong at | | | | | | |
| DEVTR | Ing METHORPHAN HYDR | | | Basis of Strength | Strengt | | | | | | |
| | METHORPHAN - UNII:73 | - | | HYDROBROMIDE | 10 mg | | | | | | |
| | EPHRINE HYDROCHL 297W6MV) | ORIDE (UNII: 04JA59TN | ISJ) (PHENYLEPHRINE - | PHENYLEPHRINE HYDROCHLORIDE | 5 mg | | | | | | |
| | | | | | | | | | | | |
| Inacti | ve Ingredients | | | | | | | | | | |
| | | Ingredient I | Name | | Strength | | | | | | |
| GLYCEF | RIN (UNII: PDC6A3C0OX |) | | | | | | | | | |
| WATER | (UNII: 059QF0KO0R) | | | | | | | | | | |
| POLYET | HYLENE GLYCOL, UN | ISPECIFIED (UNII: 3W) | Q0SDW1A) | | | | | | | | |
| | OL (UNII: 506T60A25R) | | | | | | | | | | |
| | ED NO. 40 (UNII: WZ B | | | | | | | | | | |
| | JM DIOXIDE (UNII: 15F | IX9V2JP) | | | | | | | | | |
| | C (UNII: 46N107B710) | | | | | | | | | | |
| SHELLA | | | | | | | | | | | |
| SHELLA SODIUN | HYDROXIDE (UNII: 5 | | | FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | | | | | | |
| SHELLA SODIUN FD&C Y | ELLOW NO. 6 (UNII: H | 177VE193A8) | | | | | | | | | |
| SHELLA SODIUN FD&C Y GELATII | TELLOW NO. 6 (UNII: H N, UNSPECIFIED (UNII | 177VE193A8) : 2G86QN327L) | | | | | | | | | |
| SHELLA SODIUN FD&C Y GELATII PROPYI | ELLOW NO. 6 (UNII: H N, UNSPECIFIED (UNII ENE GLYCOL (UNII: 61 | 177VE193A8) : 2G86QN327L) DC9Q167V3) | | | | | | | | | |
| SHELLA SODIUN FD&C Y GELATII PROPYI POVIDO | ELLOW NO. 6 (UNII: H N, UNSPECIFIED (UNII ENE GLYCOL (UNII: 61 NE (UNII: FZ989GH94E | 177VE193A8) : 2G86QN327L) DC9Q167V3) :) | | | | | | | | | |
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| Su | cinate cap | succinate capsule, liquid filled | | | | | | | | | |
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| Ro Ac | ute of Adm tive Ingre | ormatio inistratic dient/A | n ORAL | DPHEN - UNII:362091 | TL9D) | Basis of St ACETAMINOPHEN | rength | Strengt 325 mg | | | |
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| Ro ACI DE2 (DE PHI UNI DO | ute of Adm tive Ingre TAMINOPHE TROMETHOR TROMETHOR NYLEPHRINI :1W5297W6M | ormatio inistratic dient/Ad N (UNII: 30 RPHAN - UNI PHAN - UNI E HYDROC V) JCCINATE | n ORAL or ORAL Ctive Moiety Ingredient Name 209ITL9D) (ACETAMING DROBROMIDE (UNII: 9 :7355X3ROTS) HLORIDE (UNII: 04JA55 | 9D2RTI9KYH) 9TNSJ) (PHENYLEPHR | | ACETAMINOPHEN DEXTROMETHORP HYDROBROMIDE PHENYLEPHRINE HYDROCHLORIDE | HAN | 10 mg 5 mg | | | |
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| PROPILENC G | LYCOL (UNII: 6 | DC90167V3) | | | |
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| | NO. 10 (UNII: 1 | 35SW5USO3G) | | | |
| | II: PDC6A3C00) | | | | |
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| Product Ch | aracterist | ics | | | |
| Color | | green | Score | | no score |
| | | | Size | | 21mm |
| Flavor | | | Imprint Code | | AS;NITE |
| Contains | | | | | |
| | | | | | |
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| Packaging | | | | | |
| # Item | Markoting Star | | Marketing Start | Marketing End | |
| <u> </u> | P | ackage Descri | intion | - | |
| [#] Code | | ackage Descri | - | Date | Date |
| [#] Code 1 | 8 in 1 BLISTER | ackage Descri R PACK; Type 0: No | - | - | |
| Code | | - | - | - | |
| Code | 8 in 1 BLISTER | - | - | - | |
| 1 Code | 8 in 1 BLISTEF Product | R PACK; Type 0: No | - | - | |
| 1 Marketir | 8 in 1 BLISTER Product | R PACK; Type 0: No | t a Combination | Date | Date |
| 1 Marketir Marketir | 8 in 1 BLISTER Product | R PACK; Type 0: No | t a Combination | Date Marketing Start | Date Marketing End |
| 1 Marketir Categor | 8 in 1 BLISTER Product | R PACK; Type 0: No Nation lication Numbe Citati | t a Combination | Date Marketing Start Date | Date |
| 1 Marketir Marketir | 8 in 1 BLISTER Product | R PACK; Type 0: No Nation lication Numbe Citati | t a Combination | Date Marketing Start | Date Marketing End |
| 1 Marketir Categor | 8 in 1 BLISTER Product | R PACK; Type 0: No Nation lication Numbe Citati | t a Combination | Date Marketing Start Date | Date Marketing End |
| 1 Marketir Marketir Categor OTC monograp | 8 in 1 BLISTER Product | R PACK; Type 0: No nation lication Numbe Citati | t a Combination | Date Marketing Start Date | Date Marketing End |
| Code Code Marketir Marketir Categor OTC monograp Marketir | 8 in 1 BLISTER Product | A PACK; Type 0: No nation lication Numbe Citati | er or Monograph | Date Marketing Start Date 10/23/2020 | Date Marketing End Date |
| 1 Marketir Categor | 8 in 1 BLISTER Product | A PACK; Type 0: No nation lication Numbe Citati | er or Monograph | Date Marketing Start Date | Date Marketing End Date |

| La | be | ler - | Bayer | HealthCare | LLC. | (112117283) |
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Revised: 2/2023

Bayer HealthCare LLC.