

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

Alka-Seltzer Plus® Cold Day & Night Effervescent Tablets

Alka-Seltzer Plus® Cold Day Effervescent Tablets

Drug Facts

Active ingredients (in each tablet)

Aspirin 325 mg (NSAID)*

Dextromethorphan hydrobromide 10 mg

Phenylephrine bitartrate 7.8 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

•temporarily relieves these symptoms due to a cold with cough:

☐ • minor aches and pains ☐ • headache ☐ • cough

☐ • nasal and sinus congestion ☐ • sore throat

☐ • temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

☐ ● hives ☐ ● facial swelling ☐ ● asthma (wheezing) ☐ ● shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

● are age 60 or older

● have had stomach ulcers or bleeding problems

- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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

- if you are allergic to aspirin or any other pain reliever/fever reducer
- 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

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have
 - asthma ● 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
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for

● gout ● diabetes ● arthritis

When using this product do not exceed recommended dosage

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
 - 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
- ringing in the ears or loss of hearing occurs
- 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.

It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Directions

- adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water every 4 hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

Other information

- **each tablet contains:** sodium 416 mg
- Phenylketonurics: Contains Phenylalanine 9 mg Per Tablet
- store at room temperature. Avoid excessive heat

Inactive ingredients acesulfame potassium, anhydrous citric acid, aspartame, calcium silicate, dimethicone, docusate sodium, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

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

Alka-Seltzer Plus® Cold Night Effervescent Tablets

SPL

Active ingredients (in each tablet)

Aspirin 500 mg (NSAID)*

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine bitartrate 7.8 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

Uses

- • temporarily relieves these symptoms due to a cold:
- • minor aches and pains □ • headache □ • runny nose
- • sinus congestion and pressure □ • cough □ • sneezing
- • sore throat □ • nasal congestion
- • temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may

include:

- hives □ ● facial swelling □ ● asthma (wheezing) □ ● shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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

- if you are allergic to aspirin or any other pain reliever/fever reducer
- 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

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have
- asthma ● diabetes ● thyroid 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 a prescription drug for
 - gout • diabetes • arthritis
 - 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

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
 - feel faint ● vomit blood ● have bloody or black stools
 - have stomach pain that does not get better
 - 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
 - ringing in the ears or loss of hearing occurs
 - 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.

It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a

doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Directions

- adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water at bedtime (may be taken every 4 to 6 hours). Do not exceed 8 tablets in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

Other information

- each tablet contains: sodium 476 mg
- Phenylketonurics: Contains Phenylalanine 5.6 mg Per Tablet
- store at room temperature. Avoid excessive heat.

Inactive ingredients acesulfame potassium, anhydrous citric acid, aspartame, calcium silicate, dimethicone, docusate sodium, flavors (natural & artificial), mannitol, povidone, sodium benzoate, sodium bicarbonate

Questions or comments?

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

Package Display Label

Alka-Seltzer

PLUS®

DAY NON-DROWSY

ASPIRIN (**NSAID**) / Pain Reliever-Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Phenylephrine Bitartrate / Nasal Decongestant

- Nasal Congestion

- Headache & Body Ache
- Cough
- Sore Throat
- Sinus Pressure

12 EFFERVESCENT TABLETS

NIGHT

ASPIRIN (NSAID) / Pain Reliever-Fever Reducer

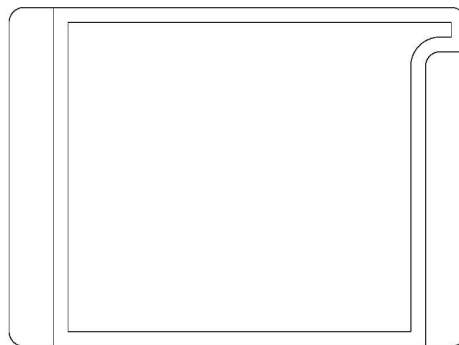
Dextromethorphan HBr / Cough Suppressant

Doxylamine Succinate / Antihistamine

Phenylephrine Bitartrate / Nasal Decongestant

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

8 EFFERVESCENT TABLETS



<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● redness or swelling is present ● new symptoms occur ● ringing in the ears or loss of hearing occurs ● cough comes back or occurs with rash or headache that lasts. There could be signs of a serious condition. ● nosebleeds, dizziness, or sleeplessness occurs 	<p>Drug Facts (continued)</p> <p>operating machinery</p> <ul style="list-style-type: none"> ● excitability may occur, especially in children <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ● an allergic reaction occurs. Seek medical help right away. ● you experience any of the following signs of stomach bleeding ● feel faint ● vomit blood ● have bloody or black stools 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● minor aches and pains ● headache ● nasal and sinus congestion ● sore throat ● temporarily reduces fever <p>Warnings</p> <p>Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product.</p>	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● minor aches and pains ● headache ● runny nose ● sinus congestion and pressure ● cough ● sneezing ● sore throat ● nasal congestion ● temporarily reduces fever <p>Warnings</p> <p>Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product.</p>
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<p>If pregnant or breast-feeding, see a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ● adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water every 4 hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor. ● children under 12 years: do not use 	<ul style="list-style-type: none"> ● have stomach pain that does not get better ● 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 ● ringing in the ears or loss of hearing occurs ● rough, cracked lips occur with rash or headache that lasts. These could be signs of a serious condition. ● nervousness, dizziness, or sleeplessness occurs <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it</p>	<p>When using this product, it changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> ● hives ● facial swelling ● asthma (wheezing) ● shock <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you</p> <ul style="list-style-type: none"> ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinner (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) 	<p>have or are recovering from a recent past or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> ● hives ● facial swelling ● asthma (wheezing) ● shock <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you</p> <ul style="list-style-type: none"> ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinner (anticoagulant) or steroid drug ● take other drugs containing prescription or
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<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed <p>Some 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.</p> <p>Do not use</p> <ul style="list-style-type: none"> ● if you are allergic to aspirin or any other pain reliever/fever reducer ● 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 <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> ● stomach bleeding warning applies to you ● you have a history of stomach problems, such as heartburn ● you have high blood pressure, heart 	<p>Drug Facts (continued)</p> <p>nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</p> <ul style="list-style-type: none"> ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed <p>Some 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.</p> <p>Do not use</p> <ul style="list-style-type: none"> ● if you are allergic to aspirin or any other pain reliever/fever reducer ● 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 <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> ● stomach bleeding warning applies to you ● you have a history of stomach problems, 	<p>Drug Facts (continued)</p> <p>disease, liver cirrhosis, or kidney disease</p> <ul style="list-style-type: none"> ● you are taking a diuretic ● you have ● asthma ● thyroid disease ● diabetes ● cough with excessive phlegm (mucus) ● persistent or chronic cough such as occurs with smoking, asthma, or emphysema ● a sodium-restricted diet <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ● taking a prescription drug for ● gout ● diabetes ● arthritis <p>When using this product do not exceed recommended dosage</p> <p>Sleep use and ask a doctor if</p> <ul style="list-style-type: none"> ● an allergic reaction occurs. Seek medical help right away. ● you experience any of the following signs of stomach bleeding ● feel faint ● vomit blood ● have bloody or black stools ● have stomach pain that does not get better ● pain, cough, or nasal congestion gets worse or lasts more than 7 days ● fever gets worse or lasts more than 3 days 	<p>Drug Facts (continued)</p> <p>such as heartburn</p> <ul style="list-style-type: none"> ● you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ● you are taking a diuretic ● you have ● asthma ● diabetes ● thyroid 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 <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ● taking a prescription drug for ● gout ● diabetes ● arthritis <p>When using this product</p> <ul style="list-style-type: none"> ● do not exceed recommended dosage ● may cause medical drowsiness ● avoid alcoholic drinks ● alcohol, sedatives, and tranquilizers may increase drowsiness ● be careful when driving a motor vehicle or
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<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> ● each tablet contains: sodium 410 mg ● Phenylephrine: Contains Phenylephrine 9 mg Per Tablet <p>● store at room temperature. Avoid excessive heat.</p> <p>Inactive ingredients acosalium potassium, anhydrous citric acid, aspartame, calcium silicate, dimethylsiloxane, croscellose sodium, kroscellose, mannitol, polydioxane, sodium benzoate, sodium bicarbonate</p> <p>Questions or comments? 1-800-998-0889 (Mon - Fri 9AM - 5PM EST)</p>	<p>Drug Facts (continued)</p> <p>may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ● adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water at bedtime (may be taken every 4 to 8 hours). Do not exceed 8 tablets in 24 hours or as directed by a doctor. ● children under 12 years: do not use <p>Other information</p> <ul style="list-style-type: none"> ● each tablet contains: sodium 476 mg ● Phenylephrine: Contains Phenylephrine 5.8 mg Per Tablet <p>● store at room temperature. Avoid excessive heat.</p> <p>Inactive ingredients acosalium potassium, anhydrous citric acid, aspartame, calcium silicate, dimethylsiloxane, croscellose sodium, favares (natural & artificial), mannitol, polydioxane, sodium benzoate, sodium bicarbonate</p> <p>Questions? 1-800-998-0399</p>
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ALKA-SELTZER PLUS COLD DAY AND NIGHT

aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-1550
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1550-20	1 in 1 CARTON; Type 0: Not a Combination Product	09/14/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 POUCH	12
Part 2	4 POUCH	8

Part 1 of 2

ALKA-SELTZER PLUS COLD DAY

aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate tablet, effervescent

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor	CITRUS	Imprint Code	ASP;DAY
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	6 in 1 CARTON		
1	2 in 1 POUCH; 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	09/14/2018	

Part 2 of 2

ALKA-SELTZER PLUS COLD NIGHT

aspirin, dextromethorphan hydrobromide, phenylephrine bitartrate, doxylamine succinate tablet, effervescent

Product Information

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: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MANNITOL (UNII: 3OWL53L36A)	
DIMETHICONE (UNII: 92RU3N3Y10)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor	LEMON	Imprint Code	ASP;NT
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
1		2 in 1 POUCH; 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	09/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/14/2018	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2025

Bayer HealthCare LLC.