

ACETAMINOPHEN, DEXTROMETHORPHAN HBR, CHLORPHENIRAMINE MALEATE-
acetaminophen, dextromethorphan hbr, chlorpheniramine maleate
CVS Pharmacy, Inc

6183-Combo Pack CVS

Day Time Powder

Drug Facts

Active ingredients (in each packet)

Acetaminophen 1000 mg

Dextromethorphan HBr 30 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Uses

- temporarily relieves these symptoms due to a common cold or flu:
- minor aches and pains • minor sore throat pain • headache
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

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 reactions. Symptoms may include:

- skin reddening • blisters • rash

If a skin 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.

- in a child under 12 years of age
- if you are allergic to acetaminophen
- 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.

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic 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 use more than directed.

Stop use and ask a doctor if

- pain or cough 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 a rash or headache that lasts
- These could be signs of a serious condition.

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed
- take every 6 hours, while symptoms persist
- Do not take more than 4 packets in 24 hours unless directed by a doctor
- dissolve contents of one packet into 8 oz. hot water, sip while hot. Consume entire drink within 10 - 15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water, stir briskly before and after heating. Do not overheat.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

Other information

- **each packet contains:** sodium 6 mg, potassium 10 mg
- Store in a dry place at 15° - 30°C (59° - 86°F).

acacia, acesulfame potassium, anhydrous citric acid, corn starch, D&C yellow #10, diacetyl tartaric and fatty acid esters of glycerol, FD&C blue #1, FD&C red #40, maltodextrin, medium chain triglycerides, natural flavor, propylene glycol, silicon dioxide, soy lecithin,

sucralose, sucrose, tartaric acid, triacetin, tribasic calcium phosphate, trisodium citrate dihydrate, yeast.

Nighttime Powder

Drug Facts

Active ingredients (in each packet)

Acetaminophen 1000 mg
Chlorpheniramine maleate 4 mg
Dextromethorphan HBr 30 mg

Purposes

Pain reliever/Fever reducer
Antihistamine
Cough suppressant

Uses

- temporarily relieves these symptoms due to a common cold or flu:
- minor aches and pains • minor sore throat pain
- headache • runny nose • cough due to minor throat and bronchial irritation
- temporarily reduces fever

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 reactions. Symptoms may include:

- skin reddening • blisters • rash

If a skin 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

- in a child under 12 years of age
- if you are allergic to acetaminophen
- 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.

Ask a doctor before use if you have

- liver disease

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- cough that occurs with too much phlegm (mucus) • cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

• do not exceed recommended dosage

- avoid alcoholic drinks
- marked drowsiness may occur
- 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 or cough 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 a rash or headache that lasts

These could be signs of a serious condition.

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed
- take every 6 hours, while symptoms persist
- Do not take more than 4 packets in 24 hours unless directed by a doctor
- dissolve contents of one packet into 8 oz. hot water, sip while hot. Consume entire drink within 10 - 15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water, stir briskly before and after heating. Do not overheat.

Age

adults and children 12 years
of age and over

Dose

one packet

Other information

- each packet contains: sodium 6 mg, potassium 10 mg
- Store in a dry place at 15° - 30°C (59° - 86°F).

acacia, acesulfame potassium, anhydrous citric acid, corn starch, D&C yellow #10, diacetyl tartaric and fatty acid esters of glycerol, FD&C red #40, maltodextrin, medium chain triglycerides, natural flavor, propylene glycol, silicon dioxide, soy lecithin, sucralose, sucrose, tartaric acid, triacetin, tribasic calcium phosphate, trisodium citrate dihydrate, yeast.

Questions? 1-800-231-4670

Draft Label

The draft label content is organized into several sections:

- Severe Flu Relief Daytime Powder (continued):**
 - Drug Facts (continued):**
 - Ask a doctor or pharmacist before use if you are pregnant or breastfeeding.
 - Stop use and ask a doctor if you have a fever that lasts more than 7 days, a cough that lasts more than 10 days, or if you have a rash or hives.
 - Drug Facts (continued):**
 - Each packet contains sodium 6 mg, potassium 10 mg.
 - Store in a dry place at 15° - 30°C (59° - 86°F).
 - Other information:**
 - Each packet contains sodium 6 mg, potassium 10 mg.
 - Store in a dry place at 15° - 30°C (59° - 86°F).
 - Inactive ingredients:** acacia, acesulfame potassium, anhydrous citric acid, corn starch, D&C yellow #10, diacetyl tartaric and fatty acid esters of glycerol, FD&C red #40, maltodextrin, medium chain triglycerides, natural flavor, propylene glycol, silicon dioxide, soy lecithin, sucralose, sucrose, tartaric acid, triacetin, tribasic calcium phosphate, trisodium citrate dihydrate, yeast.
 - Questions? 1-800-231-4670**
- Severe Flu Relief Nighttime Powder (continued):**
 - Drug Facts (continued):**
 - Some throat warning: If you have a sore throat that lasts more than 7 days, is accompanied or followed by fever, difficulty swallowing, or a white coating on your throat, stop use and ask a doctor.
 - Do not use if you are pregnant or breastfeeding.
 - Do not use if you are taking a prescription medicine such as MAOIs, 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 using this product.
 - Ask a doctor before use if you have:
 - liver disease
 - diabetes
 - trouble urinating
 - low blood sugar
 - kidney problems such as kidney stones, kidney failure, or kidney disease
 - a history of alcoholism
 - a history of seizures
 - a history of heart disease
 - a history of low blood pressure
 - a history of low sodium levels
 - a history of low potassium levels
 - a history of low calcium levels
 - a history of low magnesium levels
 - a history of low phosphorus levels
 - a history of low zinc levels
 - a history of low iron levels
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- Severe Flu Relief Nighttime Powder:**
 - Drug Facts:**
 - Active ingredients: acetaminophen 325 mg, dextromethorphan HBr 10 mg, chlorpheniramine HBr 2 mg.
 - Purposes: Pain relief, cough relief, runny nose relief.
 - Warnings: Do not use if you are pregnant or breastfeeding.
 - Do not use if you are taking a prescription medicine such as MAOIs, 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 using this product.
 - Ask a doctor before use if you have:
 - liver disease
 - diabetes
 - trouble urinating
 - low blood sugar
 - kidney problems such as kidney stones, kidney failure, or kidney disease
 - a history of alcoholism
 - a history of seizures
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 - a history of low vitamin B100 levels

ACETAMINOPHEN, DEXTROMETHORPHAN HBR, CHLORPHENIRAMINE MALEATE
 acetaminophen, dextromethorphan hbr, chlorpheniramine maleate kit

Product Information				
Product Type	HUMAN OTC DRUG		Item Code (Source)	NDC:51316-609
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-609-07	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	04/05/2024	10/21/2025
Quantity of Parts				

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	6 in 12
Part 2	1 PACKET	6 in 12

Part 1 of 2

ACETAMINOPHEN, DEXTROMETHORPHAN HBR

acetaminophen, dextromethorphan hbr powder

Product Information

Item Code (Source)	NDC:51316-604
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg

Inactive Ingredients

Ingredient Name	Strength
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL (UNII: 248HN3Z28U)	
YEAST (UNII: 3NY3SM6B8U)	
SUCROSE (UNII: C151H8M554)	
TRIACETIN (UNII: XHX3C3X673)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TARTARIC ACID (UNII: W4888I119H)	

Product Characteristics

Color	yellow (Light yellow)	Score	
Shape		Size	
Flavor	HONEY (Honey Lemon)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-604-05	6 in 1 PACKET; 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	04/05/2024	

Part 2 of 2

ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HBR

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr powder

Product Information

Item Code (Source)	NDC:51316-605
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DIACETYLTARTARIC AND FATTY ACID ESTERS OF GLYCEROL (UNII: 248HN3Z28U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
YEAST (UNII: 3NY3SM6B8U)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)
SUCROSE (UNII: C151H8M554)
TARTARIC ACID (UNII: W4888I119H)
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)
ACACIA (UNII: 5C5403N26O)
FD&C RED NO. 40 (UNII: WZB9127XOA)
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
SUCRALOSE (UNII: 96K6UQ3ZD4)
TRIACETIN (UNII: XHX3C3X673)
SOYBEAN LECITHIN (UNII: 1DI56QDM62)

Product Characteristics			
Color	yellow (Light Yellow)	Score	
Shape		Size	
Flavor	HONEY (Honey Lemon)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-605-05	6 in 1 PACKET; 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	04/05/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/05/2024	

Labeler - CVS Pharmacy, Inc (062312574)