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.

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Age	Dose
adults and children 12 years of age and over	one packet

children under 12 years of age	do not use

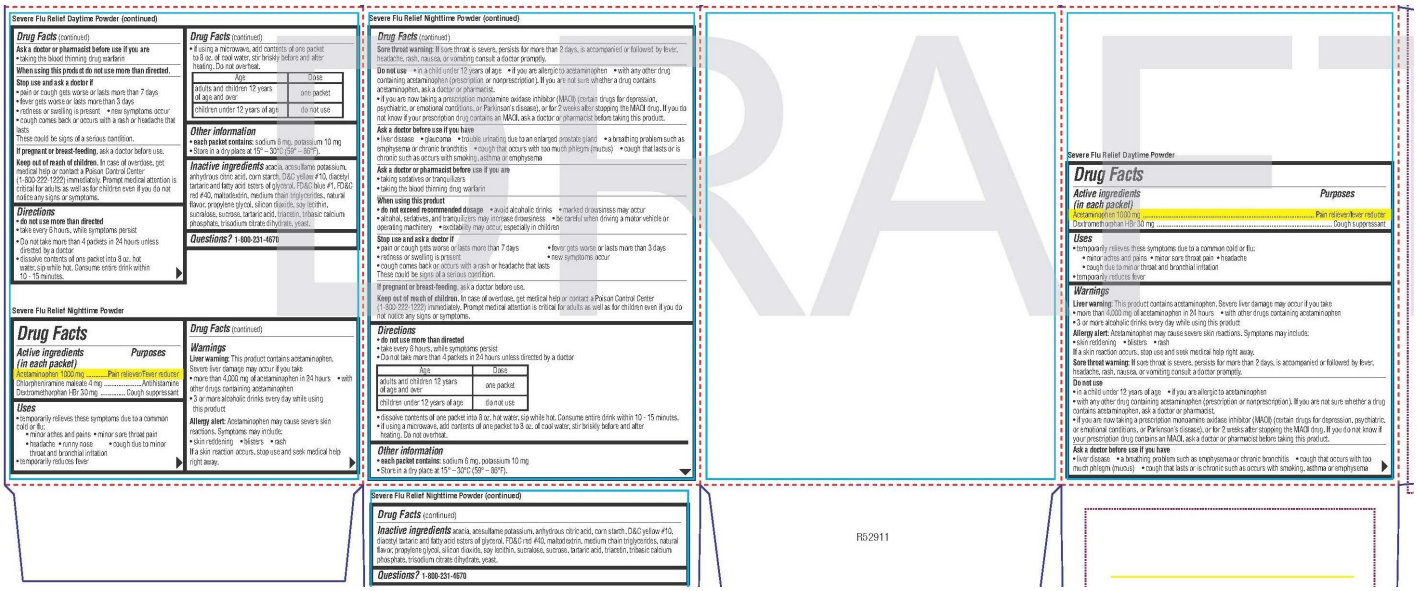
Other information

- **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 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



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	

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, 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	

Part 2 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	

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)

Revised: 4/2024 CVS Pharmacy, Inc