

**SEVERE COLD DM SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, diphenhydramine hydrochloride
Walgreen Company**

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.

Walgreen Co. Day Severe Cold DM Night Severe Cold & Flu Drug Facts

Active ingredients (in each packet) - Daytime

Acetaminophen 500 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation
- 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 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 have ever had an allergic reaction to this product or any of its ingredients
- 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 (see overdose warning)**
- take every 4 hours, while symptoms persist. Do not take more than 6 packets in 24 hours unless directed by a doctor.

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

- 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.

Other information

- **each packet contains:** potassium 10 mg and sodium 25 mg
- **phenylketonurics:** contains phenylalanine 22 mg per packet
- store at 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, D&C yellow #10, FD&C blue #1, FD&C red #40, flavors, maltodextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

1-800-719-9260

Active ingredients (in each packet)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- nasal and sinus congestion
- headache
- itchy nose or throat
- runny nose
- sneezing
- itchy, watery eyes due to hay fever
- cough due to minor throat and bronchial irritation
- 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 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 have ever had an allergic reaction to this product or any of its ingredients
- with any other drug containing acetaminophen (prescription or nonprescription). If

you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- with any other product containing diphenhydramine, even one used on skin
- 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

- thyroid disease
- high blood pressure
- liver disease
- heart disease
- diabetes
- 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

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 (see overdose warning)**
- take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

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

- 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.

Other information

- **each packet contains:** potassium 10 mg and sodium 25 mg
- **phenylketonurics:** contains phenylalanine 13 mg per packet
- store at 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, D&C yellow #10, FD&C blue #1, FD&C red #40, flavors, maltodextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

DAY & NIGHT PACK

Walgreens

WALGREENS PHARMACIST RECOMMENDED

Compare to the active ingredients in Theraflu[®] Multi-Symptom Severe Cold & Theraflu[®] Nighttime Severe Cold & Cough

MULTI-SYMPTOM

Severe Cold DM

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

PHENYLEPHRINE HCl / NASAL DECONGESTANT

- Relieves nasal congestion, sore throat pain, cough, headache, body ache & fever

NIGHTTIME

Severe Cold & Flu

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER

DIPHENHYDRAMINE HCl / ANTIHISTAMINE / COUGH SUPPRESSANT

PHENYLEPHRINE HCl / NASAL DECONGESTANT

- Relieves nasal congestion, sore throat pain, cough, headache, body ache, fever, runny nose & sneezing

6 PACKETS Green Tea & Honey Lemon Flavors

6 PACKETS Honey Lemon & White Tea Flavors

TOTAL 12 PACKETS

DAY & NIGHT PACK NDC 0363-1739-55

Walgreens

Compare to the active ingredients in **Theraflu® Multi-Symptom Severe Cold & Flu** and **Nighttime Severe Cold & Cough**

MULTI-SYMPTOM Severe Cold DM

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER
DEXTR METHORPHAN HBr / COUGH SUPPRESSANT
PHENYLEPHRINE HCl / NASAL DECONGESTANT

• Relieves nasal congestion, sore throat, pain, cough, headache, body aches & fever

6 PACKETS Green Tea & Honey Lemon Flavors

NIGHTTIME Severe Cold & Flu

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER
DIPHENHYDRAMINE HCl / ANTIHISTAMINE / COUGH SUPPRESSANT
PHENYLEPHRINE HCl / NASAL DECONGESTANT

• Relieves nasal congestion, sore throat, pain, cough, headache, body aches, fever, runny nose & sneezing

6 PACKETS Honey Lemon & White Tea Flavors

TOTAL 12 PACKETS

Severe Cold & Flu NIGHTTIME

Walgreens

MULTI-SYMPTOM Severe Cold DM

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER
DEXTR METHORPHAN HBr / COUGH SUPPRESSANT
PHENYLEPHRINE HCl / NASAL DECONGESTANT

• Relieves nasal congestion, sore throat, pain, cough, headache, body aches & fever

6 PACKETS Green Tea & Honey Lemon Flavors

W10RG0122-F

DISTRIBUTED BY: WALGREEN CO., 200 WILMOT RD., DEERFIELD, IL 60015

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ITEM 54526 WH 0106-0522-L

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CODE AREA

18655 04 C3

SEVERE COLD DM SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, diphenhydramine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1739

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1739-55	1 in 1 CARTON; Type 0: Not a Combination Product	05/24/2022	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	6
Part 2	6 PACKET	6

Part 1 of 2

SEVERE COLD DM

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride powder, for solution

Product Information

Item Code (Source) NDC:0363-1919

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
Contains	
HONEY (green tea) , LEMON (green tea)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0363-1919-00	1 in 1 PACKET; Type 0: Not a Combination Product	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/24/2022	

Part 2 of 2

SEVERE COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution

Product Information

Item Code (Source)	NDC:0363-1357
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	WHITE (mixture of white, light yellow-orange particles) , ORANGE	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1357-00	1 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 final	part341	05/24/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/24/2022	

Labeler - Walgreen Company (008965063)