

**SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr,  
phenylephrine hcl powder, for solution  
H E B**

*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.*

-----

**HEB Severe Cold & Flu Drug Facts**

**Active ingredients (in each packet)**

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 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**

## Package/Label Principal Display Panel

Compare to Theraflu® Multi-Symptom Severe Cold active ingredients

DAYTIME

Severe Cold & Flu

Acetaminophen / Pain Reliever/Fever Reducer  
 Dextromethorphan HBr / Cough Suppressant  
 Phenylephrine HCl / Nasal Decongestant

Multi-Symptom

Relief of:

Pain

Fever

Cough

Nasal Congestion

Green Tea & Honey

Lemon Flavors

6 PACKETS



Compare to *Theraflu*® Multi-Symptom Severe Cold active ingredients\*

NDC 37808-619-91



**DAYTIME  
 Severe Cold  
 & Flu**

Acetaminophen / Pain Reliever/Fever Reducer  
 Dextromethorphan HBr / Cough Suppressant  
 Phenylephrine HCl / Nasal Decongestant

**Multi-Symptom**

Relief of:

- Pain
- Fever
- Cough
- Nasal Congestion

Green Tea & Honey  
 Lemon Flavors

6 PACKETS



**DAYTIME  
 Severe Cold  
 & Flu**

Acetaminophen / Pain Reliever / Fever Reducer  
 Dextromethorphan HBr / Cough Suppressant  
 Phenylephrine HCl / Nasal Decongestant

**Multi-Symptom**

Relief of:

- Pain
- Fever
- Cough
- Nasal Congestion

Green Tea & Honey  
 Lemon Flavors

MADE IN MEXICO

MADE WITH PRIDE & CARE FOR H-E-B®  
 SAN ANTONIO, TX 78204



**100% GUARANTEE**  
 promise  
 If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

CONVENIENT RECLOSEING TAB

**Drug Facts**

**Active ingredients (in each packet)**

Acetaminophen 500 mg Pain reliever/fever reducer  
 Dextromethorphan HBr 20 mg Cough suppressant  
 Phenylephrine HCl 10 mg Nasal decongestant

**Uses**

- temporarily relieves these symptoms due to a cold:
  - runny nose and sneezing
  - 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  
 or if you take more than 3,000 mg of acetaminophen in 24 hours  
 or if you are 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, if you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.  
**Severe 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.  
**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:  
 skin redness, blisters, rash

**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, 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**

- fever gets worse or lasts more than 3 days
- irritation 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 (1-800-322-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

8550-1801

OPEN OTHER END



LOT NO.

EXP.

1 874913 11 02

**Drug Facts (continued)**

**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; stir 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
- phenylephrine: contains phenylephrine 12 mg per packet
- store at 20-25°C (68-77°F). Protect product from heat and moisture.

**Inactive ingredients:** acetaminophen, erythrosine, citric acid, aspartame, octadecyl stearate, DSC yellow #10, FD&C blue #1, FD&C red #40, flavors, malto-dextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

**Questions or comments?**

1-800-779-4269

\*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Theraflu® Multi-Symptom Severe Cold.

GLUTEN FREE

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

# SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-619
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY (green tea) , LEMON (green tea)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-619-91	6 in 1 CARTON; Type 0: Not a Combination Product	05/30/2018	

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
-----------	---------------------------------	-----------------	---------------

Category	Citation	Date	Date
OTC monograph final	part341	05/30/2018	

**Labeler** - H E B (007924756)

Revised: 11/2022

H E B