GOOD SENSE FLU AND SEVERE COLD AND COUGH NIGHTTIMEacetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution L. Perrigo 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.

Perrigo Flu & Severe Cold & Cough Drug Facts

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
- headache
- nasal and sinus congestion
- runny nose
- sneezing
- itchy nose or throat
- 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

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

Nighttime

Flu & Severe Cold & Cough

Pain Reliever-Fever Reducer

(Acetaminophen)

Antihistamine/Cough Suppressant

(Diphenhydramine HCl)

Nasal Decongestant

(Phenylephrine HCI)

Nasal Congestion

Sore Throat Pain

Cough

Headache

Body Ache

Fever

Runny Nose

Sneezing

Honey Lemon infused with White Tea Flavors

6 PACKETS

Compare to active ingredients of Theraflu® Nighttime Severe Cold & Cough





DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED

Drug Facts		
Active ingredients (in each packet) Purposes		
Acetaminophen 650 mgPain reliever/fever reducer		
Diphenhydramine HCl 25 mg		
USSS — temporally releves these symptoms due to a cold: minor ache and pains — minor ache roted pain — handsche minorache roted pain — minor ache roted pain — manuel and distus congesion — unruy rose — manuel manuel manuel disturbur rose or throat — michi wateray eyes due to tey fever — mough due to minor throat and bronchial inflation — temporally refunce fever		

mongrid due to minor throat and bronchial initiation

is imagorably recluses lever

Warnings

Liver warning: This product contains acataminophen. Severe liver damage may occur if you take
in now then 4,000 mg of acataminophen in 24 hours

with other drugs containing acataminophen in 24 hours

with other drugs containing acataminophen in 24 hours

with other drugs containing acataminophen ming this product

Allargy alands Acataminophen may cause severe side in nearctions. Symptoms may include:

a side in radio-cours shop use and seak medical help right away.

Sere throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or

followed by lever, headactup, refer, mease, or vormiting, constal a doctor promptly.

Do not use in in a child under 12 years of age

if you have now had an ellergic reaction to this product or any of its ingredients

with any other drug containing acataminophen piersecription or nonprescription). If you are not sure wither a drug contains acataminophen in prescription or nonprescription), if you are not sure wither a drug containing acateminophen piersecription or nonprescription), if you are not sure wither a drug containing acateminophen in prescription or nonprescription), if you are not sure wither a drug containing acateminophen, sake adoctor or pharmacist and the containing acateminophen in prescription or or ontains and will as in you are now taking a prescription on known layour prescription drug contains and will, ask a doctor or pharmacist before taking this product.

If you are now taking a prescription monomine and these in this product or pharmacist before taking this product.

If you had not a semply-passine or chronic bronchism

In you had not a semply-passine or chronic bronchism

In you had not a semply-passine or chronic bronchism

In you had not a semply-passine or chronic bronchism

In you had not a semply-passine or chronic bronchism

In you had not a semply-passine or chronic bronchism

In you had not a semply-passine or chronic bronchism

some years of the second years of the years of years of

OPEN OTHER END





96491 C2 C6

Drug Facts (continued)

Dri dy Pactas (Commerci)

If pregnant or breast-faeding, ask a health
professional before use.
Keep out of reach of Indiren. Overdose
warning: In case of overdose, get medical help or
contact a Pvison Control Center right away
contact a Pvison Control Center right away
critical for adults as well as for children even if you
do not not be any element commercial. do not notice any signs or symptoms.

Directions — do not use more than directed (see overdese warning) — take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

aroutou by a assetsi.	
Age	Dose .
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

12 years or age
midsolve contents of one packet into 8 oz. hot
water: sip while hot. Consume entire drink within
10-15 minutes.
mit using a microwave, add contents of one packet
to 8 oz. of coul water stir kriskly before and
after heating. Do not overheat.

Other information meach packet contains: potassium 10 mg and

■ action packet contains: potessium to ing and sodium 25 mg
■ phenylketonuries: contains phenylakanine 13 mg per packet
■ store at 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients acesultame potassium, anhydrous citric acid, aspartame, colloidal silicon doxido, B&C yellow #10, FB&C blue #1, FB&C rad #40, flavos, matlodestrin, pregelatinized starch sodium citrate, sucrose, tribesic calcium phosphate

Questions or comments? 1-800-719-9260

Gluten Free

Made in Mexico Distributed By

Perrigo_®

Allegan, MI 49010



GOOD SENSE FLU AND SEVERE COLD AND COUGH NIGHTTIME

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0113-0964 **Route of Administration** ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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: 230V73Q5G9)		
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	
Shape		Size	
Flavor		Imprint Code	
Contains			

Ш	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0113-0964- 91	6 in 1 CARTON; Type 0: Not a Combination Product	09/17/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/17/2010	

Labeler - L. Perrigo Company (006013346)

Revised: 8/2021 L. Perrigo Company