FLU RELIEF THERAPY NIGHT TIME- acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid Family Dollar (FAMILY WELLNESS)

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.

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/Cough suppressant

Nasal decongestant

Uses

- temporarily relieves
 - minor aches and pains
 - sneezing
 - headache
 - minor sore throat pain
 - itchy, watery eyes
 - nasal and sinus congestion
 - runny nose
 - cough due to minor throat and bronchial irritation
 - itchy nose or throat
- temporarily reduces fever

Warnings

Allergy alert: Acetaminophen may cause severe skin reactions. symptoms may include:

- skin reddening
- blisters
- rash

Liver warning: This product contains acetaminophen. Severe liver damage may occur

if you take:

- more than 6 doses (12 tablespoons or 180 mL) in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

- to make a child sleepy
- 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.
- with any other product containing diphenhydramine, even one used on skin
- with any other product containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease
- glaucoma
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- cough accompanied by excessive phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are taking

- the blood thinning drug warfarin
- sedatives or tranquilizers

When using this product

- do not use more than directed (see overdose warning)
- 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

- redness or swelling is present
- nervousness, dizziness, or sleeplessness occurs
- pain, cough or nasal congestion gets worse or lasts more than 7 days

- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with a fever, 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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see overdose warning)
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- mL=milliliter
- keep dosing cup with product
- adults and children 12 years and over
 30 mL every 4 hours
- children under 12 years of age; do not use

Other information

- each 30 mL contains: potassium 10 mg
- each 30 mL contains: sodium 14 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

acesulfame potassium, alcohol, citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavors, glycerin, maltitol solution, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Theraflu® Nighttime Severe Cold & Cough*

For ages 12 & over

Nighttime

Flu Relief Therapy

Severe Cold and Flu

Acetaminophen 650 mg

Pain reliever; fever reducer

Diphenhydramine HCl 25 mg

Cough suppressant; antihistamine

Phenylephrine HCl 10 mg

Nasal decongestant

Alcohol 10%

Cherry Flavor

FL OZ (mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Theraflu® Nighttime Severe Cold & Cough.

DISTRIBUTED BY: FAMILY DOLLAR SERVICES, INC

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VISIT FAMILYDOLLAR.COM

Product Label



Family Wellness Nighttime Flu Relief Therapy

FLU RELIEF THERAPY NIGHT TIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:55319-317	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name			Basis of Stre	ngth	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)		ACETAMINOPHEN		650 mg in 30 mL	

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)	DIPHENHYDRAMINE	25 mg
(DIPHENHYDRAMINE - UNII:8GTS82S83M)	HYDROCHLORIDE	in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients					
Ingredient Name ACESULFAME POTASSIUM (UNII: 230V73Q5G9)					Strength
ALCOHOL (UNII:		1. 230 (73Q3G3)			
ANHYDROUS CI					
EDETATE DISOL					
FD&C BLUE NO					
FD&C RED NO.					
GLYCERIN (UNII:	-	- ,			
MALTITOL (UNII:					
PROPYLENE GL	COL (UNII: 6DC	9Q167V3)			
WATER (UNII: 05					
SODIUM BENZO					
TRISODIUM CIT	RATE DIHYDRA	FE (UNII: B22547B95K)			
Product Cha	racteristics	5			
Color		Score			
Shape Size					
Flavor		CHERRY	Imprint Code		
Contains					
Packaging					
# Item Code	F	Package Description		Marketing Start Date	Marketing En Date
1 NDC:55319- 317-08	245 mL in 1 BC Combination P	BOTTLE, PLASTIC; Type 0: Not a Product		07/31/2015	
	Informa	tion			
Marketing					
Marketing Marketing Category		ation Number or Mor Citation	nograph	Marketing Start Date	Marketing End Date

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 10/2021