

**REESES ONETAB COLD AND FLU - acetaminophen diphenhydramine hydrochloride phenylephrine hydrochloride tablet
REESE PHARMACEUTICAL CO.**

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

Keep out of reach of children.

Temporarily relieves symptoms associated with the common cold, flu, hay fever and other respiratory allergies
nasal and sinus congestion
itching of the nose or throat
minor aches and pains
sneezing and runny nose
itchy, watery eyes
headaches

LIVER WARNING : THIS PRODUCT CONTAINS ACETAMINOPHEN. SEVERE LIVER DAMAGE MAY OCCUR IF ADULT TAKES MORE THAN 6 DOSES IN 24 HOURS WHICH IS THE MAXIMUM DAILY AMOUNT, A CHILD TAKES MORE THAN 5 DOSES IN 24 HOURS , WHICH IS THE MAXIMUM DAILY AMOUNT , TAKEN WITH OTHER DRUGS CONTAINING ACETAMINOPHEN ,ADULT HAS 3 OR MORE ALCOHOLIC DRINKS EVERYDAY WHILE USING THIS PRODUCT

Directions

adults and children 12 years of age and older: take 1 caplet every 4 hours as needed.
Do not exceed 6 doses In a 24 hour period or as directed by a doctor

children 6 to under 12 years of age: take 1/2 caplet every 4 hours as needed.
Do not exceed 5 doses In a 24 hour period or as directed by a doctor

children under 6 years of age: consult a doctor

Do not use _ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist _ more than directed _ if you are taking sedatives or tranquilizers without first consulting your doctor _ if you are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's Disease) or for two weeks after stopping the MAOI drug if are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product

Ask a doctor before use if the user has liver damage persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis, or emphysema, cough is accompanied by excessive phlegm (mucus), high blood pressure, thyroid disease, glaucoma, diabetes, heart disease, a breathing problem such as emphysema or chronic bronchitis, difficulty In urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug "Warfarin"

When using this product

marked drowsiness may occur _ excitability may occur, especially in children

alcohol, sedatives and tranquilizers may increase the drowsiness effect _ avoid alcoholic drinks _ use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur,
 - pain symptoms do not improve after 7 days for adults or 5 days for children or tend to recur
 - _ cough and cold symptoms do not improve within 7 days or recur
 - _ symptoms are accompanied by fever that lasts more than 3 days
 - _ sore throat is severe or persists for more than 2 days
 - _ new symptoms occur or redness, swelling, rash, persistent headache, nausea or vomiting occur.
- These could be signs of a serious condition

If pregnant or breast feeding, ask a health professional before use.

In case of overdose, get medical help or contact a Poison Control Center immediately. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

croscarmellose sodium, hydroxypropylmethylcellulose, magnesium silicate, magnesium stearate,

microcrystalline cellulose, polyvinylpyrrolidone, silica, sodium starch glycolate, starch,

stearic acid, titanium dioxide.

Other Information

_ store at 15'-30'C (59'-86'F)

ACETAMINOPHEN 650 mg

DIPHENHYDRAMINE HYDROCHLORIDE 25 mg

30 DOSES PER PACKAGE

REESE'S ONE TAB™

INTENSE STRENGTH

COLD & FLU

Relieves all major cold, allergy, and flu-like symptoms

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INTENSE STRENGTH

COLD & FLU

Relieves all major cold, allergy, and flu-like symptoms

Acetaminophen
Diphenhydramine HCl
Phenylephrine HCl

- PAIN RELIEVER/ FEVER REDUCER
- ANTIHISTAMINE/ COUGH SUPPRESSANT
- NASAL DECONGESTANT

30 DYE FREE CAPLETS

STRONGER THAN LEADING BRANDS



Drug Facts (continued)

- cough & cold symptoms do not improve within 7 days or recur
- symptoms are accompanied by fever that lasts more than 3 days
- sore throat is severe or persists for more than 2 days
- new symptoms occur or redness, swelling, rash, persistent headache, nausea or vomiting occur. **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 doctor right away. Poison Control Center or local poison control center can be reached at 1-800-368-5773. For more information, call toll-free 1-800-368-5773. See important information about this product on the label or package. This information does not take the place of reading the label. Read the label carefully as well as children even if you do not notice any signs or symptoms.

Directions

- adults and children 12 years of age and older: take 1 caplet every 4 hours as needed. Do not exceed 6 doses in a 24-hour period or as directed by a doctor
- children 6 to under 12 years of age: take 1/2 caplet every 4 hours as needed. Do not exceed 5 doses in a 24-hour period or as directed by a doctor
- children under 6 years of age: consult a doctor.

Other Information

- store at 15°-30°C (59°-86°F)

Inactive Ingredients: croscarmellose sodium, hypromellose, magnesium silicate, magnesium stearate, microcrystalline cellulose, polyvinylpyrrolidone, sodium starch glycolate, starch, stearic acid, titanium dioxide

Rev. 6/09 CPEGR07

Caution: Do not use if imprinted seal under cap is broken or missing.

Drug Facts

Active Ingredients (per caplet)

- Acetaminophen HCl, 650 mg
- Diphenhydramine HCl, 25 mg
- Phenylephrine HCl, 10 mg

Purpose

Pain Reliever/Fever Reducer
Cough Suppressant
Allergy Relief
Nasal Decongestant

Uses temporarily relieves symptoms associated with the common cold, flu, hay fever and other respiratory allergies:

- sneezing & runny nose
- nasal & sinus congestion
- itching of the nose or throat
- minor aches and pains
- headaches
- reduces fevers
- reduces liver

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 6 doses in 24 hours, which is the maximum daily amount. Do not take more than 6 doses in 24 hours. Do not take with other drugs containing acetaminophen. ■ adult has 3 or more alcoholic drinks everyday while using this product.

Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ more than directed ■ if you are taking sedatives or tranquilizers without the advice of your doctor. ■ if you are taking a prescription medicine called MAO inhibitors (MAOI) for depression or high blood pressure, or if you are taking a prescription medicine called Parkinson's Disease. Or for two weeks after stopping the MAOI drug. If you are taking any other prescription drug, ask your doctor or pharmacist. ■ if you are taking any other prescription drug, ask your doctor or pharmacist. ■ if you are taking any other prescription drug, ask your doctor or pharmacist. ■ if you are taking any other prescription drug, ask your doctor or pharmacist.

Ask a doctor before use if the user has ■ liver damage ■ persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough is accompanied by excessive phlegm (mucus) ■ high blood pressure ■ thyroid disease ■ diabetes ■ difficulty in urination due to enlargement of the prostate gland or chronic bronchitis ■ difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if the user is ■ taking the blood thinning drug "Warfarin"

When using this product

- marked drowsiness may occur ■ excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase the drowsiness effect ■ avoid alcoholic drinks ■ use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- pain symptoms do not improve after 7 days for adults or 5 days for children or tend to recur

Distributed By
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Questions? 800-321-7178



0 23513 81330 1

PHENYLEPHRINE HYDROCHLORIDE 10 MG

ACETAMINOPHEN 650 mg _ PAIN RELIEVER ; FEVER REDUCER

DIPHENHYDRAMINE HYDROCHLORIDE 25 mg _ ANTIHISTAMINE

PHENYLEPHRINE HYDROCHLORIDE 10 mg _ NASAL DECONGESTANT

REESES ONETAB COLD AND FLU

acetaminophen diphenhydramine hydrochloride phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10956-813
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

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL (CAPLET)	Size	17mm
Flavor		Imprint Code	RC;CPE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-813-01	1 in 1 CARTON		
1	NDC:10956-813-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/05/2010	

Labeler - REESE PHARMACEUTICAL CO. (004172052)

Registrant - REESE PHARMACEUTICAL CO. (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
REESE PHARMACEUTICAL CO.		004172052	repack, relabel

Establishment

Name	Address	ID/FEI	Business Operations
CONTRACT PHARMACAL		057795122	manufacture

Revised: 8/2010

REESE PHARMACEUTICAL CO.