REESES ONETAB ALLERGY AND SINUS - 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

Acetaminophen 650 mg
Diphenhydramine Hydochloride 25 mg
Phenylephrine Hydrochloride 10 mg

croscarmellose sodium,htpromellose,magnesium silicate,magnesium stearate,

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

stearic acid,titanium dioxide.

Pain Reliever/Fever Reducer

Antihistamine/Cough Suppressant

Nasal Decongestant

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 ago: consult a doctor

KEEP OUT OF REACH OF CHILDREN

Do not use _ with any other drug containing acetaminophen (prescription or nonpreescription). 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 MAD I drug if are uncertain whether your prescription drug contains an MAOI, consuit 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 orlend 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.

Other Information

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

REESES ONETAB ALLERGY AND SINUS

acetaminophen diphenhydramine hydrochloride phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10956-812
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
hypromellose (UNII: 3NXW29V3WO)	
magnesium silicate (UNII: 9B9691B2N9)	
magnesium stearate (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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:10956-812-01	1 in 1 CARTON		
1	NDC:10956-812-30	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.