TIME-GESIC- acetaminophen and diphenhydramine hydrochloride tablet, coated Time-Cap Labs, Inc

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.

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.

Ask a doctor before use if you have liver disease.

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

Stop use and ask a doctor if

pain persists for more than 10 days; fever persists for more than 3 days (unless directed by a doctor); condition worsens or new symptoms appear; redness or swelling is present. These could be signs of a serious condition.

If pregnant or nursing, as with any drug, seek the advise of a health professional before using this product.

Keep this and all drugs out of reach of children.

Directions

adults and children 12 years and over: take 1 to 2 tablets every six hours while symptoms last. Maximum daily dose is 9 tablets in 24 hours unless directed by a doctor.

children under 12 years: Do not use this product in children under 12 years of age; this will provide more than the recommended dose (overdose) and could cause serious health problems.

Other information

- store at 25° C (77° F) excursions permitted between 15°-30° C (59°-86° F)
- use by expiration date on package
- avoid excessive heat
- sodium free

colloidal silicon dioxide, crospovidone, fd&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, povidone, pregelatinized starch, stearic acid

Uses: temporarily releives mnor aches and pains due to:

headache, backache, muscular aches, arthritis pain, colds, flu, fever, toothache, premenstrual cramps.

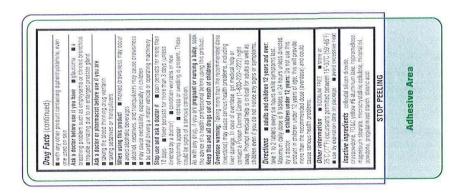
Pain Reliever-fever reducer-antihistamine

Warnings:

Liver warning: This product contains acetaminophen. Severe liver damage may occur if: adult or child 12 years and older takes more than 12 tablets in 24 hours, which is the maximum daily amount; taking with other durgs containing acetaminophen; adult has 3 or more alcoholic drinks every day while using this product.

Each tablet contains:

acetaminophen 325 mg





TIME-GESIC

acetaminophen and diphenhydramine hydrochloride tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:49483-356	
Route of Administration	ORAL	DEA Sche dule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	325 mg	
DIPHENHYDRAMINE HYDRO CHLO RIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
COLLOIDAL SILICON DIOXIDE			
CROSPOVIDONE			
FD&C YELLOW NO. 6			
HYPROMELLOSES			
MAGNESIUM STEARATE			
CELLULOSE, MICRO CRYSTALLINE			
POVIDONE			
STARCH, PREGELATINIZED CORN			
STEARIC ACID			

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	TCL106
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-356-09	90 in 1 BOTTLE, PLASTIC		
2	NDC:49483-356-00	100000 in 1 CARTON		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/18/2012	

Labeler - Time-Cap Labs, Inc (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
Time-Cap Labs, Inc		037052099	manufacture(49483-356)	

Revised: 1/2014 Time-Cap Labs, Inc