DOLOGESIC - acetaminophen, phenyltoloxamine citrate, alcohol liquid
Llorens Pharmaceutical International Division

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 tablespoonful (15 mL)	**Purpose**
Acetaminophen, USP 500 mg/15mL	Pain Reliever/Fever Reducer
Phenyltoloxamine Citrate, USP 30 mg/15mL	Pain Reliever
Alcohol, USP..... 5%	Pharmaceutical Aid

Uses

- for the temporary relief of minor aches and pains associated with
- - headache
  - backache
  - muscular aches
  - premenstrual and menstrual cramps
  - the common cold and flu
  - toothache
  - for minor pains from arthritis
  - temporarily reduces fever

Alcohol Warning: If you consumer 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.

Acetaminophen may cause liver damage.

When using this product

- drowsiness may occur
- avoid alcoholic beverages
- alcohol and sedatives may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Ask a doctor before use if you are

- taking tranquilizers or sedatives

Ask a doctor before use if you have

- glaucoma
- emphysema
- asthma
- chronic pulmonary disease
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if

- pain persists for more than 10 days, or redness is present, or in conditions affecting children 12 years of age, consult a physician immediately
- if relief does not occur within 3 days, discontinue use and consult a physician

Do not give to children under 3 years of age or more use for more than 10 days unless directed by a physician

Do not take this product for more than 10 days and do not take for fever for more than 3 days unless directed by a physician

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

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

Directions Do not exceed 8 tablespoons in any 24-hour period or as directed by a doctor

adults and children 12 years of age and older	take 1 or 2 tablespoons every 4 to 6 hours
children under 12 years of age	Consult a physician; do not give this product to children under 12 years of age. This product will provide more than the recommended dose (overdose) of non-aspirin and could cause serious health problems

Other information store at controlled room temperature 20 - 25 degrees C (68 - 77 degrees F); excursions permitted to 15 - 30 degrees C (59 - 86 degrees F) [See USP Controlled Room Temperature]. Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering.

Inactive ingredients: Citric Acid, Ethanol (5 percent by volume), FD and C Yellow Number 6, Glycerin, Menthol, Methylparaben, Peach Flavor, Potassium Sorbate, Propylene Glycol, Propylparaben, Purified Water and Sugar.

Questions or Comments? 1-866-595-5598

Llorens International Division, Miami, Fl 33166

DOLOGESIC

acetaminophen, phenyltoloxamine citrate, alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-512
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 15 mL
PHENYLTOLOXAMINE CITRATE (UNII: 8UE48MJH8M) (PHENYLTOLOXAMINE - UNII:K65LB6598J)	PHENYLTOLOXAMINE CITRATE	30 mg in 15 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-512-06	177 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/01/1994	

Labeler - Llorens Pharmaceutical International Division (037342305)

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