DOLOGESIC DF- acetaminophen, phenyltoloxamine citrate tablet
LLORENS PHARMACEUTICALS 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 caplet) **Purpose**

Acetaminophen ..... 500 mg ..... Analgesic

Phenyltoloxamine Citrate ..... 30 mg ..... Hay fever relief

Uses

- For the temporary relief of minor aches and pains associated with
- headache
- muscular aches
- backaches
- minor arthritis pain
- common cold
- toothaches
- menstrual cramps
- temporarily reduces fever
- itchy and watery eyes due to hay fever

Warnings

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

Liver Warning: This product contains Acetaminophen, Sever liver damage may occur if you take

- more than 6 tablets 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

Do not use

- with any other drug containing acetaminophen (prescription or non-prescription).
  If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- if you are allergic to acetaminophen or any of the inactive ingredients in the product
- for more than 10 days for pain, unless directed by a doctor
- for more than 3 days for fever, unless directed by a doctor

Ask a doctor before use:

- if you have liver disease
- if you are taking the thinning drug warfarin

Stop using this product and ask doctor if:

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

- These could be signs of a serious condition.

Warnings:

- May cause drowsiness: alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product
- Do not take this product if you are taking sedatives or tranquilizers without consulting a doctor
- Use caution when driving motor vehicles or operating machinery

Keep out of reach of children.

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

Directions: Do not exceed recommended dosage

AGE	Dose
adults and children 12 years of age and over	take 1 tablet every 4-6 hours. Do not take more than 6 tablets in 24 hours, or as directed by a doctor
children under 12 years of age	Do not use in children under 12 years of age. This will provide more than the recommended dose (overdose) of acetaminophen and could cause liver damage

Overdose Warning: Taking more than the recommended dose (overdose), may cause liver damage. In case of accidental overdose, contact a physician or 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.

Other information: Store at room temperature 15-30 degrees C (59-86 degrees F).

Tamper Evident: Do not use if there is evidence of tampering.

Inactive Ingredients: Povidone, pregelatinized starch, stearic acid, magnesium stearate, silicon dioxide.

Questions or Comments?1-866-595-5598

DOLOGESIC DF

acetaminophen, phenyltoloxamine citrate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-110
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PHENYLTOLOXAMINE CITRATE (UNII: 8UE48MJH8M) (PHENYLTOLOXAMINE - UNII:K65LB6598J)	PHENYLTOLOXAMINE CITRATE	30 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	LLORENS
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54859-110-10	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/01/2009	

Labeler - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Revised: 4/2012 LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION