

DOLOGESIC DF- acetaminophen, dextbrompheniramine maleate tablet
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.

Active Ingredients

(in each caplet)

Acetaminophen 500 mg

Dextbrompheniramine Maleate 1 mg

Purpose

Pain reliever/fever reducer

antihistamine

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

Warnings

Liver Warning: □ This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 capsules 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

□ **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.

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

Ask a doctor or pharmacist before use:

- if you are taking the blood thinning drug warafin
- if you have liver disease

Stop using this product and ask a doctor if:

- pain gets worse or last more than 10 days
- fever gets worse or last more than 3 days
- new symptoms occur
- redness or swelling is present
- these could be signs of a serious condition

Keep out of reach of children

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

Directions

Overdose Warning: Taking more than 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

Do not exceed recommended dosage

Age	Dose
adults and children 12 years of age and over	Take 2 caplets every 4-6 hours. Do not take more than 8 caplets 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 acetaminphen and could cause liver damage

Inactive ingredients

magnesium stearate, microcrystalline cellulose, sodium starch glycolate, tricalcium phosphate

Questions or comments

1-866-595-5598

Drug Facts

Active Ingredients (in each caplet) **Purpose**
 Acetaminophen..... 500 mgPain Reliever/Fever reducer
 Dextbrompheniramine Maleate..... 1 mgAntihistamine

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. Severe liver damage may occur if you take ■ more than 8 caplets 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 blood thinning drug warfarin.
Stop using this product and ask a doctor if:
 ■ pain gets worse or last more than 10 days ■ fever gets worse or last more than 3 days ■ new symptoms occur ■ redness or swelling is present ■ These could be signs of a serious condition.



NDC 54859-010-01
DOLOGESIC-DF
ACETAMINOPHEN
DEXBROMPHENIRAMINE MALEATE
 DYE FREE • SUGAR FREE

- ANALGESIC
- FEVER REDUCER

www.Llorensparm.com

100 CAPLETS



Drug Facts (continued)

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 your doctor. ■ Use caution when driving motor vehicle or operating machinery.

Keep out of reach of children.
Overdose Warning: Taking more than 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.
 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 2 caplets every 4-6 hours. Do not take more than 8 caplets 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.

Other information • store at room temperature 15° - 30°C (59° - 86°F).
 Tamper evident: Do not use if there is evidence of tampering.
Inactive ingredients: Magnesium stearate, microcrystalline cellulose, sodium starch glycolate, tricalcium phosphate.
Questions or Comments? 1-808-595-5598
Distributed By: Llorens International Division, Miami, FL 33147

Lot # **NON-VARNISH**
 Exp. Date: Rev. 12/15

DOLOGESIC DF

acetaminophen, dextbrompheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	20mm
Flavor		Imprint Code	LLORENS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-010-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2016	

Labeler - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2020

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