

ACTIDOGESIC DF- acetaminophen, dexbrompheniramine maleate tablet
Actipharma, Inc

ACTIDOGESIC® - DF

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen, 500 mg

Dexbrompheniramine 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 • itchy and watery eyes due to hay fever.

Warnings

Liver Warning: This product contains **acetaminophen**. Severe liver damage may occur if you take • more than 8 caplets (4,000 mg) 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

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash

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

Do not use • with any other drug containing **acetaminophen** (prescription or non-prescription) this will provide more than the recommended dose (overdose) of **acetaminophen** and could cause serious health concerns. 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.

Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.

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 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.

If pregnant or breast-feeding, ask a health professional before use. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Keep out of reach of children.

Directions • Do not exceed recommended dosage

Adults and children 12 years of age and older	Take 2 caplets every 4 to 6 hours as needed, do not exceed 8 caplets in 24 hours, or as directed by a doctor, do not use for more than 10 days unless directed by a doctor.
Children under 12 years of age	Do not use.

Other Information

- Tamper Evident. Do not use if inner seal is torn, broken, or missing
- Store at controlled room temperature 15°- 30°C (59°- 86°F)
- Avoid excessive heat or humidity

Inactive Ingredients: Magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

- **ANALGESIC • FEVER REDUCER**
- **ANTIHISTAMINE**

Contains the same active ingredients as Dologesic[®] - DF*

SUGAR FREE

DYE FREE

ActiPharma

COMMITTED TO HEALTH AND WELL-BEING

Manufactured in the USA

for ActiPharma, Inc.

Dorado, PR 00646.

Tel: (787) 608-0882

* Dologesic® - DF is a registered trademark of Llorens Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Llorens Pharmaceutical Corp.

Packaging

NDC 63102-403-10

ACTIDOGESIC®-DF

• ANALGESIC • FEVER REDUCER
• ANTIHISTAMINE

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Each caplet contains:

Acetaminophen.....500 mg
Dexbrompheniramine Maleate...1 mg

**SUGAR FREE
DYE FREE**

Net Contents: 100 Caplets

Lot # _____
Exp. Date _____

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Peel Here

Drug Facts (continued)

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DRUG FACTS LABEL

Drug Facts

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ACTIDOGESIC DF

acetaminophen, dexbrompheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63102-403
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
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MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white	Score	2 pieces
Shape	capsule	Size	17mm
Flavor		Imprint Code	A403
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63102-403-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/10/2020	

Labeler - Actipharma, Inc (079340948)

Revised: 10/2023

Actipharma, Inc