

ACTIDOGESIC- dexbrompheniramine maleate, acetaminophen tablet
ACTIPHARMA, LLC

ACTIDOGESIC®

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, 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.

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis

- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

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

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.

Keep out of reach of children. 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.

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:

FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, glycerol mono and dicaprylocaprate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyvinyl alcohol graft polyethylene glycol copolymer, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or Comments?

Call weekdays from 8:00 AM - 4:00 PM, AST at **1-787-608-0882**

• ANALGESIC • FEVER REDUCER • ANTIHISTAMINE

Contains the same active ingredients as Dologesic®

SUGAR FREE

ActiPharma

COMMITTED TO HEALTH AND WELL-BEING

WWW.ACTIPHARMA.NET

Manufactured in the USA with imported ingredients for ActiPharma, LLC San Juan, PR 00917

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

Packaging

Drug Facts

Active ingredients (in each caplet) **Purpose**

Acetaminophen, 500 mg.....Pain reliever/Fever reducer
 Dexbrompheniramine Maleate, 1 mg.....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, 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 over-the-counter)

Peel Here

NDC 63102-402-10

ACTIDOGESIC®

• ANALGESIC • FEVER REDUCER
 • ANTIHISTAMINE

Contains the same active ingredients as Dologesic®

Each caplet contains:
Acetaminophen500 mg
Dexbrompheniramine Maleate....1 mg

SUGAR FREE

Net Contents: 100 Caplets



ActiPharma
 COMMITTED TO HEALTH AND WELL-BEING
 WWW.ACTIPHARMA.NET
 Manufactured in the USA with imported ingredients for ActiPharma, LLC San Juan, PR 00917
 Rev. 04/25

Drug Facts Label

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen, 500 mg.....Pain reliever/Fever reducer Dexbrompheniramine Maleate, 1 mg.....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, 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.

Drug Facts (continued)

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.

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

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

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. **Keep out of reach of children.** 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

Do not use • with any other drug containing acetaminophen (prescription or

Peel Here

for children even if you do not notice any signs or symptoms.

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: FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, glycerol mono and dicaprylocaprate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyvinyl alcohol graft polyethylene glycol copolymer, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or Comments?

Call weekdays from 8:00 AM - 4:00 PM, AST at 1-787-608-0882

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

ACTIDOGESIC

dexbrompheniramine maleate, acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63102-402
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYVINYL ALCOHOL GRAFT POLYETHYLENE GLYCOL COPOLYMER (3:1; 45000 MW) (UNII: 23ZQ42JZZH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	2 pieces
Shape	capsule	Size	17mm
Flavor		Imprint Code	A402
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63102-402-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/14/2016	

Labeler - ACTIPHARMA, LLC (079340948)

Registrant - ACTIPHARMA, LLC (079340948)