ACTIDOGESIC- dexbrompheniramine maleate, acetaminophen tablet
ACTIPHARMA, INC

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:Dexbrompheniramine Maleate 1 mg, Acetaminophen 1mg

Antihistamine, Pain reliever/fever reducer

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.

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.

Do not use

• with any other drug containing acetaminophen (prescription or nonprescription) 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.

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.

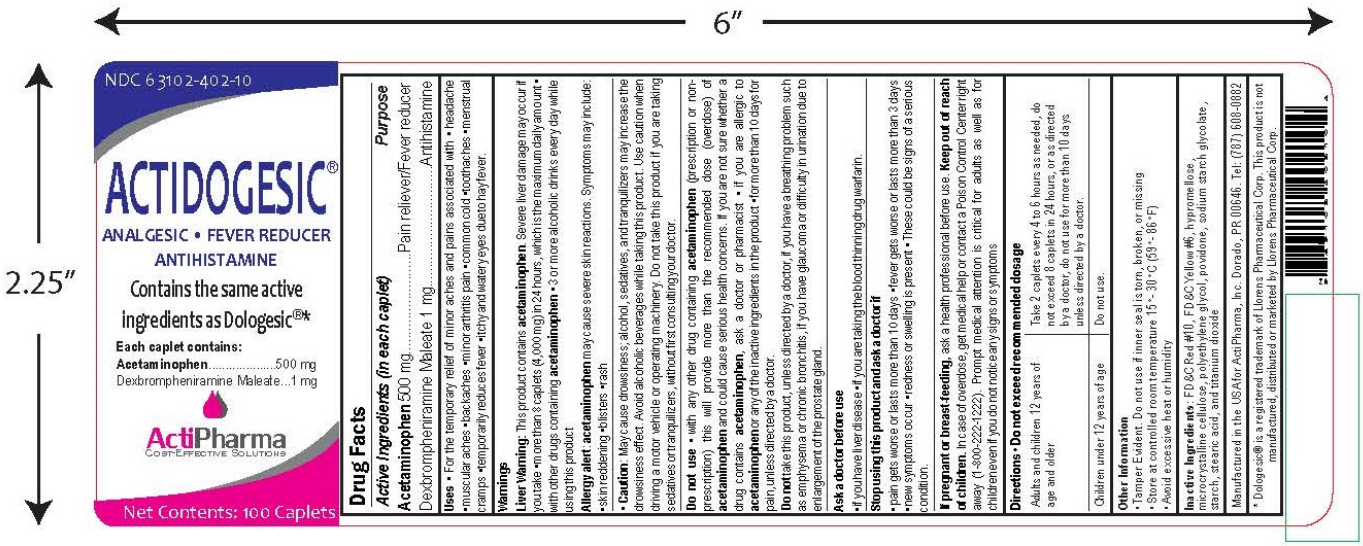
Other Information

• 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 #40, FD&C Yellow #6, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid, and titanium dioxide



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 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
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 final	part341	10/14/2016	

Labeler - ACTIPHARMA, INC (079340948)

Registrant - ACTIPHARMA, INC (079340948)

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