BIOGESIC- acetaminophen, dexbrompheniramine maleate tablet Advanced Generic Corporation

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

Pain Reliever/Fever Reducer

Dexbrompheniramine maleate 1 mg

Antihistamine

Purpose

Antihistamine

Nasal Decongestant

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

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.

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 pregnant or breast-feeding, ask a Health Professional before use.

Directions: Do not exceed recommended dosage

	Take 2 caplets every 4-6 hours. Do not take more than 8 caplets in 24 hours, or as directed by a doctor.
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.

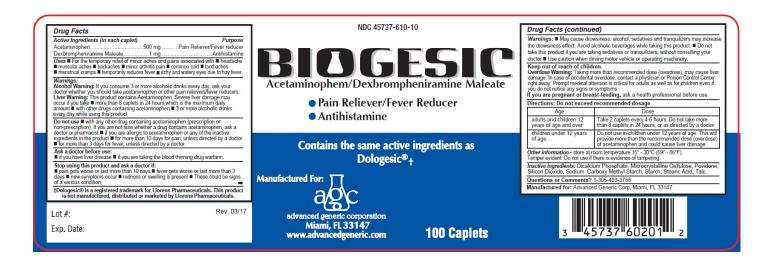
Uses

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

Inactive ingredients: Idicalcium phasphate, microcrystalline cellulose, povidone, silicon dioxide, sodium carboxymethyl starch, starch, stearic acid, talc.

Questions or comments?

1-305-403-3788



BIOGESIC

acetaminophen, dexbrompheniramine maleate tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-610	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg	
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9 UT29 BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg	

Inactive Ingredients	
Ingredient Name	Strength
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
PO VIDO NE (UNII: FZ989 GH94E)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS311)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	
Contains			

Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:45737-610-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 17		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	0 1/0 1/20 17	

Labeler - Advanced Generic Corporation (831762971)