

**BIOGESIC- acetaminophen, dextbrompheniramine 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.*

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**Drug Facts**

**Active ingredients (in each caplet)**

Acetaminophen 500 mg

Dextbrompheniramine maleate 1 mg

**Purpose**

Pain Reliever/Fever Reducer

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 and 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**

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.

**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

**Inactive ingredients:** Dicalcium phosphate, microcrystalline cellulose, povidone, silicon dioxide, sodium carboxymethyl starch, starch, stearic acid, talc.

**Questions or comments?**

1-305-403-3788

**Drug Facts**

**Active Ingredients (in each caplet)**

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 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 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.

†Dologesic® is a registered trademark for Llorens Pharmaceuticals. This product is not manufactured, distributed or marketed by Llorens Pharmaceuticals.

Lot #: \_\_\_\_\_ Rev. 03/17  
 Exp. Date: \_\_\_\_\_

NDC 45737-610-10

# BIOGESIC

Acetaminophem/Dexbrompheniramine Maleate

- Pain Reliever/Fever Reducer
- Antihistamine

**Contains the same active ingredients as**  
**Dologesic® +**

**Manufactured For:**

advanced generic corporation  
 Miami, FL 33147  
 www.advancedgeneric.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:** Dicalcium Phosphate, Microcrystalline Cellulose, Povidone, Silicon Dioxide, Sodium Carboxy Methyl Starch, Starch, Stearic Acid, Talc.

**Questions or Comments?** 1-305-403-3788  
 Manufactured for: Advanced Generic Corp, Miami, FL 33147

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**BIOGESIC**  
 acetaminophen, dexbrompheniramine maleate tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45737-610
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-610-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2017	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/2017	

**Labeler** - Advanced Generic Corporation (831762971)