

DOLOGEN- dexbrompheniramine maleate, acetaminophen tablet

Kramer Novis

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.

Dolgen

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen 650 mg

Dexbrompheniramine Maleate 2 mg

Purpose

Analgesic, Antipyretic (Fever Reducer)

Antihistamine

Uses:

temporarily relieves minor aches and pains due to: • headache • common cold • toothache • backache • muscular aches • menstrual cramps • minor pain of arthritis • relieves runny nose, and sneezing, itching of the nose or throat, and itchy watery eyes due to hay fever or other respiratory allergies. Temporarily reduces fever.

Warnings

Liver Warning: This product contains **acetaminophen**. Severe liver damage may occur if you take: • more than 6 caplets (3,900 mg) in 24 hours • 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. If skin reaction occurs, stop use and seek medical help right away.

Do not use : with any other product 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. **When using this product do not exceed recommended dose.**

Ask a doctor before use if you have: • liver disease • breathing problems such as emphysema or chronic bronchitis • glaucoma or difficulty in urination due to enlargement of the prostate gland.

Ask a doctor or pharmacist before use if you are taking: • the blood thinning drug warfarin • sedatives or tranquilizers

While using this product: • excitability may occur • drowsiness may occur; 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.

Stop use and ask a doctor if: • pain gets worse or lasts for 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

Overdose warning: 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:

Adults and children 12 years of age and older:	take 1 caplet every 4 - 6 hours or as directed by a doctor Do not exceed 6 caplets in 24 hours
Children under 12 years : Consult a doctor	

Other Information:

- Tamper Evident. Do not use if seal is broken.
- Store at controlled room temperature 15° to 30°C (59° to 86°F). • Avoid excessive heat and humidity.

Inactive Ingredients:

corn starch, hydroxypropylmethylcellulose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate and stearic acid

Pain Reliever

Fever Reducer

Antihistamine

Sugar & Dye Free

Manufactured in the USA for Kramer-Novis, San Juan, PR 00917. Tel: (787) 767-2072

www.kramernovis.com

Packaging

EXP. DATE

LOT #

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Acetaminophen 650 mg Analgesic, Antipyretic (Fever Reducer)	
Dexbrompheniramine Maleate 2 mg Antihistamine	
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Ask a doctor before use if you have: - liver disease - breathing problems such as emphysema or chronic bronchitis - glaucoma or difficulty in urination due to enlargement of the prostate gland.	
Ask a doctor or pharmacist before using if you are taking: - the blood	

NDC 52083-481-90

DOLOGEN

**Pain Reliever
Fever Reducer
Antihistamine**

Acetaminophen 650 mg
Dexbrompheniramine Maleate 2 mg

Sugar & Dye Free

NET CONTENTS: 90 CAPLETS



Pharmaceuticals within reach of patients

Drug Facts (continued)

thinning drug warfarin - sedatives or tranquilizers.

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If pregnant or breast-feeding, ask a health professional before use. **KEEP OUT OF REACH OF CHILDREN.**

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Manufactured in the USA for: REV 06/18 Kramer-Novis, San Juan, PR 00917, Tel: (787) 767-2072 www.kramernovis.com



Drug Facts		Drug Facts (continued)	
Active Ingredients (in each caplet)	Purpose	While using this product: - excitability may occur - drowsiness may occur; 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.	Stop use and ask a doctor if: - pain gets worse or lasts for more than 10 days - fever gets worse or lasts for more than 3 days - new symptoms occur - redness or swelling is present. These could be a sign of serious conditions.
Acetaminophen 650 mg Analgesic, Antipyretic (Fever Reducer)		Stop use and ask a doctor if: - pain gets worse or lasts for more than 10 days - fever gets worse or lasts for more than 3 days - new symptoms occur - redness or swelling is present. These could be a sign of serious conditions.	If pregnant or breast-feeding, ask a health professional before use. KEEP OUT OF REACH OF CHILDREN.
Dexbrompheniramine Maleate 2 mg Antihistamine		Other Information: - Tamper Evident. Do not use if packet is torn, out or opened - Store at controlled room temperature 15° to 30° C (59° to 86° F) - Avoid excessive heat and humidity	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.
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Kramer-Novis Pharmaceuticals within reach of patients

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NET CONTENTS: 90 CAPLETS

Sugar & Dye Free

Acetaminophen 650 mg
Dexbrompheniramine Maleate 2 mg

**Pain Reliever
Fever Reducer
Antihistamine**

DOLOGEN

NDC 52083-481-02 Physician's Sample

DOLOGEN
dexbrompheniramine maleate, acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-481
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	2 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

Color	white (WHITE)	Score	2 pieces
Shape	CAPSULE (D)	Size	19mm
Flavor		Imprint Code	D
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-481-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2011	
2	NDC:52083-481-02	2 in 1 PACKET; Type 0: Not a Combination Product	10/11/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/11/2011	

Labeler - Kramer Novis (090158395)

Registrant - Kramer Novis (090158395)

Revised: 12/2018

Kramer Novis