

**G-DOLOGEN- acetaminophen, dextbrompheniramine maleate 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.*

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**G-DOLOGEN**

**Drug Facts**

***Active Ingredients (in each caplet)***

**Acetaminophen 650 mg**

Dextbrompheniramine 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 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 for 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. (1-800-222-122)  
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 directed by a doctor. <b>Do not exceed 6 caplets in 24 hours.</b> |
| Children under 12 years:                       | consult 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.

Compare to Dologen<sup>®</sup>

**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](http://www.kramernovis.com)

**Packaging**

EXP. DATE

LOT #

| Drug Facts  |                |
|---|----------------|
| <b>Active Ingredients (in each caplet)</b>  | <b>Purpose</b> |
| Acetaminophen 650 mg ..... Analgesic, Antipyretic (Fever Reducer)   |                |
| Dexbrompheniramine Maleate 2 mg ..... Antihistamine   |                |
| <b>Uses:</b> 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.                              |                |
| <b>Warnings: Liver Warning:</b> 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 while using this product.   |                |
| <b>Allergy alert: acetaminophen</b> may cause severe skin reactions. Symptoms may include: - skin reddening - blisters - rash. If skin reaction occurs, stop use and seek medical help right away.  |                |
| <b>Do not use:</b> 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. <b>When using this product do not exceed recommended dose.</b> |                |
| <b>Ask a doctor before use if you have:</b> - liver disease - breathing problems such as emphysema or chronic bronchitis - glaucoma or difficulty in urination due to enlargement of the prostate gland.  |                |
| <b>Ask a doctor or pharmacist before using if you are taking:</b> - the blood   |                |

NDC 52083-681-90

**G-DOLOGEN**

Compare to Dologen®

**Pain Reliever  
Fever Reducer  
Antihistamine**

Acetaminophen ..... 650 mg  
Dexbrompheniramine Maleate ..... 2 mg

**Sugar & Dye Free**

NET CONTENTS: 90 CAPLETS

**Drug Facts (continued)**

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 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.**

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 directed by a doctor. **Do not exceed 6 caplets in 24 hours.**

Children under 12 years: consult 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.

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



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**G-DOLOGEN**

acetaminophen, dexbrompheniramine maleate tablet

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:52083-681 |
| <b>Route of Administration</b> | 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 400 (UNII: B697894SGQ)             |          |
| POVIDONE K30 (UNII: U725QWY32X)                        |          |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                        |          |

**Product Characteristics**

|                 |                     |                     |          |
|-----------------|---------------------|---------------------|----------|
| <b>Color</b>    | white (IVORY WHITE) | <b>Score</b>        | 2 pieces |
| <b>Shape</b>    | CAPSULE (D)         | <b>Size</b>         | 19mm     |
| <b>Flavor</b>   |                     | <b>Imprint Code</b> | D        |
| <b>Contains</b> |                     |                     |          |

**Packaging**

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:52083-681-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 08/27/2014           |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 08/27/2014           |                    |

**Labeler** - KRAMER NOVIS (090158395)**Registrant** - KRAMER NOVIS (090158395)

Revised: 12/2018

KRAMER NOVIS