

**DOLOGEN- acetaminophen, dextbrompheniramine maleate tablet**  
**Kramer Novis**

-----  
**DOLOGEN® for adults**

***Drug Facts***

***Active ingredients (in each tablet)***

Acetaminophen 500 mg  
Dextbrompheniramine maleate 2mg

***Purpose***

Pain reliver/fever reducer  
Antihistamine

***Uses***

- for the temporary relief of minor aches and pains associated with
  - headache • the common cold • toothache • muscular aches • backache •
- premenstrual and menstrual cramps • the minor pain from arthritis and reduces fever.
- for the temporary relief of • runny nose • sneezing • itching of the nose or throat • itchy, watery eyes due to hay fever.

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take • more than 6 tablets 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 • blister • rash. if a skin reaction occurs, stop use and seek medical help right away.

**Do not use** • with any other drug containing acetaminophen (prescription or nonprescription). 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 • this product unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland • if you are taking sedatives or tranquilizers, without first consulting your doctor.

**Ask a doctor before use if you have** liver disease

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

**When using this product** • 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

**Stop use and ask a doctor if** • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • redness or swelling in present • any new symptoms appear

**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. 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 tablet every 4 to 6 hours as needed, do not exceed 6 tablets in 24 hours, or as directed by a doctor.
children under 12 years of age	consult a doctor

***Other information:***

• tamper evident feature: do not use if security seal is torn, broken, or missing • store at controlled room temperature: 15°- 30° C (59° - 86° F) • avoid excessive heat or humidity

***Inactive ingredients:***

magnesium stearate, microcrystalline cellulose, sodium starch glycolate, steric acid

***Questions or comments?***

**1-787-767-2072**

Call weekdays from 8:00 am to 4:00 pm AST.

**You may also report serious side effects to this phone number**

Sugar & Dye Free

**Manufactured for:** Kramer Novis

San Juan, PR 00917

Made in USA with imported ingredients

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

Peel the label from the bottom right corner for Drug Facts (continued).

## Packaging

### Front Panel

**Drug Facts**

**Active ingredients (in each tablet) Purpose**

Acetaminophen 500 mg.....Pain reliever/fever reducer  
Dexbrompheniramine maleate 2mg.....Antihistamine

**Uses**

- for the temporary relief of minor aches and pains associated with
- headache • the common cold • toothache • muscular aches • backache • premenstrual and menstrual cramps
- the minor pain from arthritis and reduces fever.
- for the temporary relief of • runny nose • sneezing
- itching of the nose or throat • itchy, watery eyes due to hay fever.

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take • more than 6 tablets 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. If a skin reaction occurs, stop use and seek medical help right away.

Peel the label from the bottom right corner for Drug Facts (continued).

Manufactured for Kramer Novis  
San Juan, PR 00917  
Made in USA with imported ingredients  
www.kramernovis.com  
Rev. 08/25

3 5 2 0 8 3 1 4 8 3 9 0 5

NDC 52083-483-90

**DOLOGEN®**  
for adults

**Acetaminophen,  
Dexbrompheniramine  
Maleate**

**Pain Reliever-  
Fever Reducer  
Antihistamine**

Sugar & Dye Free  
**Net Contents 90 Tablets**

**Kramer Novis**  
Pharmaceuticals within reach of patients

### Drug Facts Label

**Drug Facts**

**Active ingredients (in each tablet) Purpose**

Acetaminophen 500 mg.....Pain reliever/fever reducer  
Dexbrompheniramine maleate 2mg.....Antihistamine

**Uses**

- for the temporary relief of minor aches and pains associated with
- headache • the common cold • toothache • muscular aches • backache • premenstrual and menstrual cramps
- the minor pain from arthritis and reduces fever.
- for the temporary relief of • runny nose • sneezing
- itching of the nose or throat • itchy, watery eyes due to hay fever.

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take • more than 6 tablets 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. If a skin reaction occurs, stop use and seek medical help right away.

**Drug Facts (continued)**

**Do not use** • with any other drug containing acetaminophen (prescription or nonprescription). 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 • this product unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland • if you are taking sedatives or tranquilizers, without first consulting your doctor.

**Ask a doctor before use if you have** liver disease

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

**When using this product** • 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

**Stop use and ask a doctor if** • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • redness or swelling is present • any new symptoms appear

**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. 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 tablet every 4 to 6 hours as needed, do not exceed 6 tablets in 24 hours, or as directed by a doctor.
children under 12 years of age	consult a doctor

**Other information:** • tamper evident feature: do not use if security seal is torn, broken, or missing • store at controlled room temperature: 15° - 30° C (59° - 86° F) • avoid excessive heat or humidity

**Inactive ingredients:** magnesium stearate, microcrystalline cellulose, sodium starch glycolate, stearic acid

**Questions or comments? 1-787-767-2072**  
Call weekdays from 8:00 am to 4:00 pm AST.  
**You may also report serious side effects to this phone number**

## DOLOGEN

acetaminophen, dextbrompheniramine maleate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52083-483
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>DEXBROMPHENIRAMINE MALEATE</b> (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	capsule	<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:52083-483-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/15/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

OTC Monograph Drug	M012	12/15/2025	
--------------------	------	------------	--

**Labeler** - Kramer Novis (090158395)

**Registrant** - Kramer Novis (090158395)

Revised: 12/2025

Kramer Novis