DOLOGEN 325- acetaminophen, dexbrompheniramine 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.

DOLOGEN® 325

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen 325 mg

Dexbrompheniramine Maleate 1 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. Temporarily relieves runny nose, and sneezing, itching of the nose or throat, and itchy watery eyes due to hay fever or other respiratory allergies.

Warnings:

Liver Warning: This product contains **acetaminophen.** Severe liver damage may occur if: • you take more than 10 tablets (3,250 mg) in 24 hours in adults or 5 tablets (1,625 mg) in 24 hours for children • Adults take more than 4,000 mg of **acetaminophen** in 24 hours • your child takes more than 5 doses in 24 hours, which is the maximum daily amount • you take with other drugs containing **acetaminophen** • you take 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 a skin reaction occurs, stop use and seek medical help right away.

Do not use : with 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.

Do not give this product to children who have breathing problems such as chronic bronchitis, or who have glaucoma, without first consulting a doctor.

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 especially in children • 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 in adults • pain gets worse or lasts for more than 5 days in children under 12 years • fever gets worse or lasts for more than 3 days • new symptoms occur • redness or swelling is present. These could be signs 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 2 tablets every 4 to 6 hours as needed, do not exceed 10 tablets in 24 hours, or as directed by a doctor. Do not use for more than 10 days unless directed by a doctor.
Children 6 to under 12 years of age:	Take 1 tablet every 4 to 6 hours, not to exceed 5 tablets in 24 hours, or as directed by a doctor.
Children under 6 years of age:	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, microcrystalline cellulose, povidone, sodium starch glycolate, and stearic acid

NEW IMPROVED FORMULA

- **Pain Reliever**
- **Fever Reducer**
- **Antihistamine**

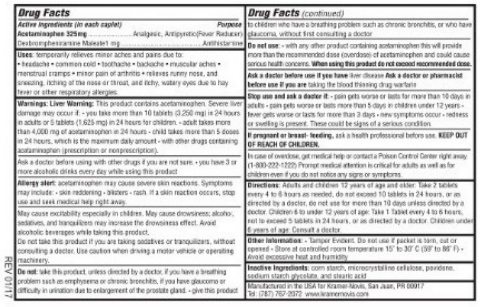
Sugar & Dye Free

Manufactured in the USA for

Kramer-Novis, San Juan, Puerto Rico 00917 Tel: 787-767-2072

www.kramernovis.com

Packaging



DOLOGEN 325

acetaminophen, dexbrompheniramine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-482
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white (ivory white)	**Score**	no score
Shape	CAPSULE (D)	**Size**	14mm
Flavor		**Imprint Code**	D
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52083-482-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
2	NDC:52083-482-02	2 in 1 PACKET; 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