

DOLODENT TOOTHACHE FOR ADULTS- acetaminophen, caffeine tablet
Pharmadel LLC

Dolodent Toothache (V)

Drug Facts

Drug Facts

Active ingredients and Purposes

<i>Active ingredients</i>	<i>Purposes</i>
Acetaminophen 500 mg.....	Pain reliever/fever reducer
Caffeine 65 mg.....	Pain reliever aid

Uses

For the temporary relief of minor aches and pains due to:

- toothache
- headache
- and to reduce fever

Warnings

Liver warning: This product contains **acetaminophen**. Severe liver damage may occur if you take

- more than **8 tablets in 24 hours**, which is the maximum daily amount for this product
- 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.

Caffeine: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine -containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

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 allergic to any of the ingredients in this product
- on children under 12 years of age

Ask a doctor before use if you have

- liver disease

Ask a doctor before use if you are

- taking the blood thinning drug warfarin

Stop use and ask a doctor or dentist 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 breastfeeding,

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

OVERDOSE WARNING: Taking more than the recommended dose (overdose) may cause liver damage. 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

- **do not take more than directed (see OVERDOSE WARNING)**
- adults and children 12 years of age and older: take 2 tablets, every 6 hours while symptoms last. Do not take more than **8 tablets in 24 hours**
- children under 12 years of age: do not use

Other information

- store between 68°-77°F (20°-25°C)

Inactive ingredients

croscarmellose sodium, microcrystalline cellulose 101, povidone k30, silicon dioxide, stearic acid, water

Questions?

+1-866-359-3478 (M-F) 9 AM to 5 PM EST or www.pharmadel.com

Distributed by / Distribuido por:

PHARMADEL LLC

New Castle, DE, 19720

Principal Display Panel

DoloDent
Toothache • Dolor de muelas

Acetaminophen 500mg - Caffeine 65mg
Acetaminofén 500mg • Cafeína 65mg

- Toothache
- Dolor de Muelas
- Fever reducer
- Reduce la fiebre

DoloDent[®]
Toothache
for adults
Acetaminophen 500mg - Caffeine 65mg

- Toothache
- Fever reducer

24 Tablets

DOLODENT TOOTHACHE FOR ADULTS

acetaminophen, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-435
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

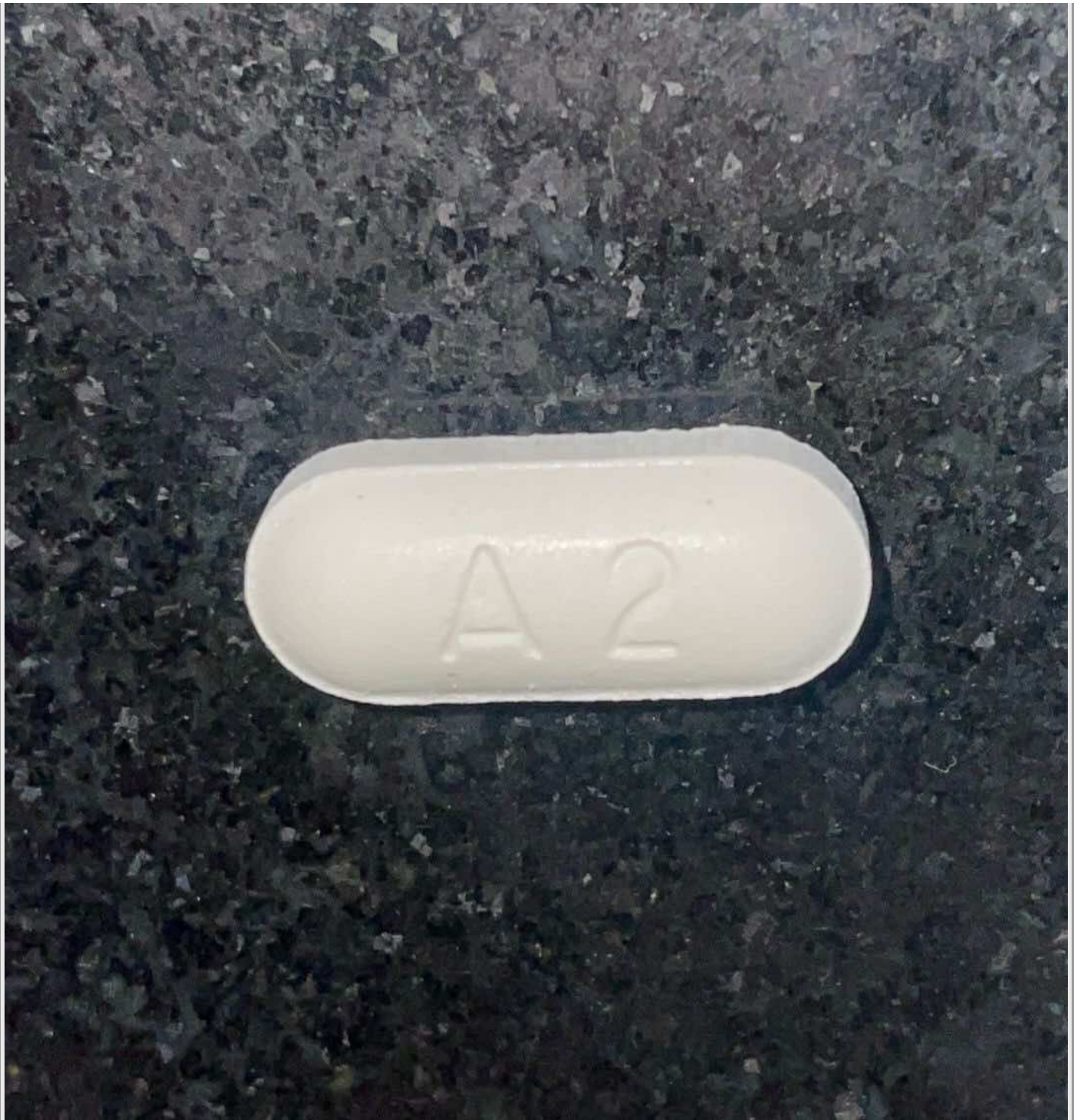
Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE K30 (UNII: U725QWY32X)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE ((Capsule-Shaped Tablet))	Size	18mm
Flavor		Imprint Code	A2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-435-24	1 in 1 CARTON	07/30/2024	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/30/2024	

Labeler - Pharmadel LLC (030129680)