

**DOLOFIN- acetaminophen tablet**  
**Menper Distributors Inc.**

*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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**Active Ingredient (in each tablet)**

□ Acetaminophen 325 mg

**□ Purpose**

□ Pain reliever/Fever reducer

**□ Uses**

□ For the temporary relief of minor aches and pains associated with

- headache
- muscular aches
- minor arthritis pain
- menstrual cramps
- common cold
- temporarily reduces fever
- backaches
- toothaches

**□ Warnings:**

**Alcohol warning:**

- □ If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

**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.

**□ 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 you are allergic to acetaminophen or any of the inactive ingredients in the product.
- for more than 10 days for pain, unless directed by a doctor.
- for more than 3 days for fever, unless directed by a doctor.

**□ Ask a doctor before use**

- □ if you have liver disease
- if you are taking the blood thinning drug warfarin.

**Stop using this product and ask a doctor if:**

- □ symptoms do not improve
- pain or fever persists or get worse
- New symptoms occur

- Redness or swelling is present
- These could be signs of a serious condition

**As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.**

**Keep this and all drugs out of the reach of children**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions:**

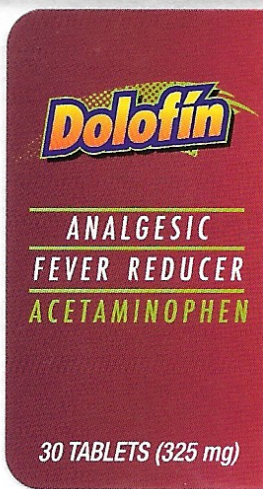
- Do not take more than 6 tablets in 24 hours

Adults and children 12 years and over Take 1 tablet every 4-6 hours as needed, or as directed by a doctor.

Children under 12 years Do not use this adult extra strength product in children under 12 years of age. This will provide more than the recommended dose (overdose) of acetaminophen and could cause liver damage.

**Inactive ingredients** Dicalcium phosphate, microcrystalline cellulose, povidone, silicon dioxide, sodium carboxy methyl starch, stearic acid, talc

Questions: Call 1-800-560-5223 M-F 9AM - 4PM Eastern



<b>Drug Facts</b>
<b>Active Ingredient in each tablet Purpose</b> Acetaminophen 325 mg.....Analgesic/Fever Reducer
<b>Uses</b> For the temporary relief of minor aches and pains associated with: headache ■ muscular aches ■ minor arthritis pain ■ menstrual cramps ■ common cold ■ temporarily reduces fever ■ backaches ■ toothaches
<b>Warnings: Do not exceed recommended dose</b> <b>Alcohol Warnings:</b> ■ If you consume 3 or more alcoholic drinks every day, ask your doctor if you take more than 6 tablets in 24 hours, which is the maximum daily dose. ■ When you should take acetaminophen or other pain relievers/fever reducers, Acetaminophen may cause liver damage. <b>Liver Warnings:</b> This product contains Acetaminophen. Severe liver damage may occur if you take ■ more than 6 tablets in 24 hours, which is the maximum daily dose. ■ more than 10 days for pain, unless directed by a doctor. ■ more than 3 days for fever, unless directed by a doctor. <b>Do not use:</b> ■ with any other drug containing acetaminophen (prescription or non-prescription) if you are not sure whether a drug contains acetaminophen or any of the inactive ingredients in this product. ■ for more than 10 days for pain, unless directed by a doctor. ■ for more than 3 days for fever, unless directed by a doctor.
<b>Ask a doctor before use:</b> ■ if you have liver disease ■ if you are taking the blood thinning drug warfarin.
<b>Stop using this product and ask a doctor if:</b> ■ symptoms do not improve ■ pain or fever persists or get worse ■ new symptoms occur ■ redness or swelling is present. These could be signs of a serious condition. <b>Keep this and all drugs out of the reach of children.</b> <b>Overdose Warning:</b> Taking more than recommended dose (overdose), may cause liver damage. In case of accidental overdose, contact a physician or Poison Control Center immediately. Prompt medical attention is necessary for adults as well as for children even if you do not notice any signs or symptoms. As with all drugs, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.
<b>Directions:</b> Do not take more than 6 tablets in 24 hours Adults and children 12 years of age and older Take 1 tablet every 4-6 hours as needed, or as directed by a doctor. Children under 12 years Do not use this adult extra strength product in children under 12 years of age. This will provide more than the recommended dose (overdose) of acetaminophen and could cause liver damage.
<b>Other Information</b> Store at room temperature. Tamper-Evident: Do not use if safety seal over bottle is broken or missing.
<b>Inactive Ingredients</b> Dicalcium Phosphate, Microcrystalline Cellulose, Povidone, Silicon Dioxide, Sodium Carboxy Methyl Starch, Stearic Acid, Talc.

Rev. 03/17  
Distributed by member Distributors Inc.  
11421 NW 107 St., Suite #24, Miami, FL 33178  
www.memberdistributors.com  
Lot #: \_\_\_\_\_  
Exp.: \_\_\_\_\_

**DOLOFIN**  
acetaminophen tablet

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-420
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
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### Inactive Ingredients

Ingredient Name	Strength
ANHYDRO US DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

### Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	555
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-420-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/2017	

**Labeler** - Menper Distributors Inc. (101947166)

**Registrant** - Menper Distributors Inc. (101947166)

### Establishment

Name	Address	ID/FEI	Business Operations
Lex Inc.		046172888	manufacture(53145-420)