

ACETAMINOPHEN 325MG- acetaminophen tablet
Marlex Pharmaceuticals 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.

Acetaminophen 325mg

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen USP 325 mg

Purpose

Pain Reliever/ Fever Reducer

Uses

Temporary relieves minor aches and pains due to:

- The common cold
- Headache
- Backache
- Minor pain of arthritis
- Toothache
- Muscular aches
- Premenstrual and menstrual cramps

* Temporarily reduces fever.

Warnings

Liver warning: this product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 this product.

Drug Facts (continued)

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.

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.
- 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.**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. (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 directed (see overdose warning)****Adults and Children 12 years and over:**

- Take 2 tablets every 6 hours while symptoms last.
- Do not take more than 12 tablets in 24 hours, unless directed by a doctor.
- Do not use for more than 10 days unless directed by a doctor.

Children 6-11 years :

- Take 1 tablet every 4 to 6 hours while symptoms last.
- Do not take more than 5 tablets in 24 hours.

Children under 6 years :

- ask a doctor.

Other Information

- Store between 20-25 °C (68-77 °F).
- See end panel for lot number and expiration date.

Inactive Ingredients

Povidone, Pregelatinized Starch, Sodium Carboxymethyl Starch, Stearic Acid

Distributed by:

Marlex Pharmaceuticals, Inc.
New Castle, DE 19720

PRINCIPAL DISPLAY PANEL

NDC 10135-0123-01

Acetaminophen

325 mg

100 TABLETS

NDC 10135-0123-01

ACETAMINOPHEN 325 mg

Compare to
Regular Strength **TYLENOL**®
active ingredient*

DO NOT USE IF IMPRINTED SAFETY SEAL
UNDER CAP IS BROKEN OR MISSING.

100 TABLETS



*This product is not manufactured or distributed by McNeil Consumer Products Company. Marlex Pharmaceuticals is not affiliated with the owner of the Trademark Regular Strength Tylenol®.



Drug Facts

Active Ingredient (in each tablet)
Acetaminophen USP 325 mg Pain Reliever/
Fever Reducer

Uses

- To reduce fever and for the temporary relief of minor aches and pains due to:
 - Headache
 - Backache
 - The common cold
 - Premenstrual and menstrual cramps
- Muscular ache
- Minor pain of arthritis
- Toothache
- Temporarily reduces fever

Warnings

- Liver warning:** this product contains acetaminophen. Severe liver damage may occur if
 - adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
 - child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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 this product.

REV 04/18 HP **Drug Facts** (continued on back)

<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have liver disease.</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • Pain gets worse or lasts more than 10 days in adults and children. • Pain gets worse or lasts more than 5 days in children under 12 years. • Fever gets worse or lasts more than 3 days. • New symptoms occur. • Redness or swelling is present. <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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. (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.</p> <p>Directions Do not take more than directed</p> <p>Adults and Children 12 years and over:</p> <ul style="list-style-type: none"> • Take 2 tablets every 4 to 6 hours while symptoms last. • Do not take more than 12 tablets in 24 hours. <p>Children 6-11 years:</p> <ul style="list-style-type: none"> • Take 1 tablets every 4 to 6 hours while symptoms last. • Do not take more than 5 tablets in 24 hours. <p>Children under 6 years: Do not use this adult regular strength product in children under 6 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.</p> <p>Other Information</p> <ul style="list-style-type: none"> • store between 20-25°C (68-77°F). • see end panel for lot number and expiration date. <p>Inactive Ingredients Pregelatinized Starch, Povidone, Stearic Acid, Sodium Carboxymethyl Starch.</p> <p>Distributed by: Marlex Pharmaceuticals, Inc. New Castle, DE 19720</p>

ACETAMINOPHEN 325MG

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-123
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	MLX123
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-123-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2018	

Labeler - Marlex Pharmaceuticals Inc (782540215)

Revised: 2/2021

Marlex Pharmaceuticals Inc