MEDLINE ACETAMINOPHEN- acetaminophen tablet
Medline Industries, 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.

Medline Acetaminophen 325 mg Tablets

Tamper Evident Packaging

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Active ingredient (in each tablet)

Acetaminophen USP, 325 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

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

- adults take more than 4.000 mg in 24 hours
- 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

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 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

Ask a doctor before use if the user has

liver disease.

Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- 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

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:

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 4 to 6 hours while symptoms last • do not take more than 10 tablets in 24 hours, unless directed by a doctor • do not take for more than 10 days unless directed by a doctor
children 6 years to under 12 years	• take 1 tablet every 4 to 6 hours while symptoms last • do not take more than 5 tablets in 24 hours, unless directed by a doctor • do not take for more than 5 days unless directed by a doctor
children under 6 years	• ask a doctor

Other information

- store at room temperature in a dry place

Inactive ingredients

povidone, pregelatinzed starch, sodium starch glycolate, stearic acid

Questions?

f you have any questions or comments, or to report an adverse event, please contact **1-800-MEDLINE**

(633-5463)

www.medline.com

Manufactured in the USA with US and foreign components for:

Medline Industries, Inc., Three Lakes Drive, Northfield, IL 60093

1-800-MEDLINE

† This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol®.

MEDLINE

NDC 53329-642-30

† *Compare to the active Ingredient in Regular Strength Tylenol®*

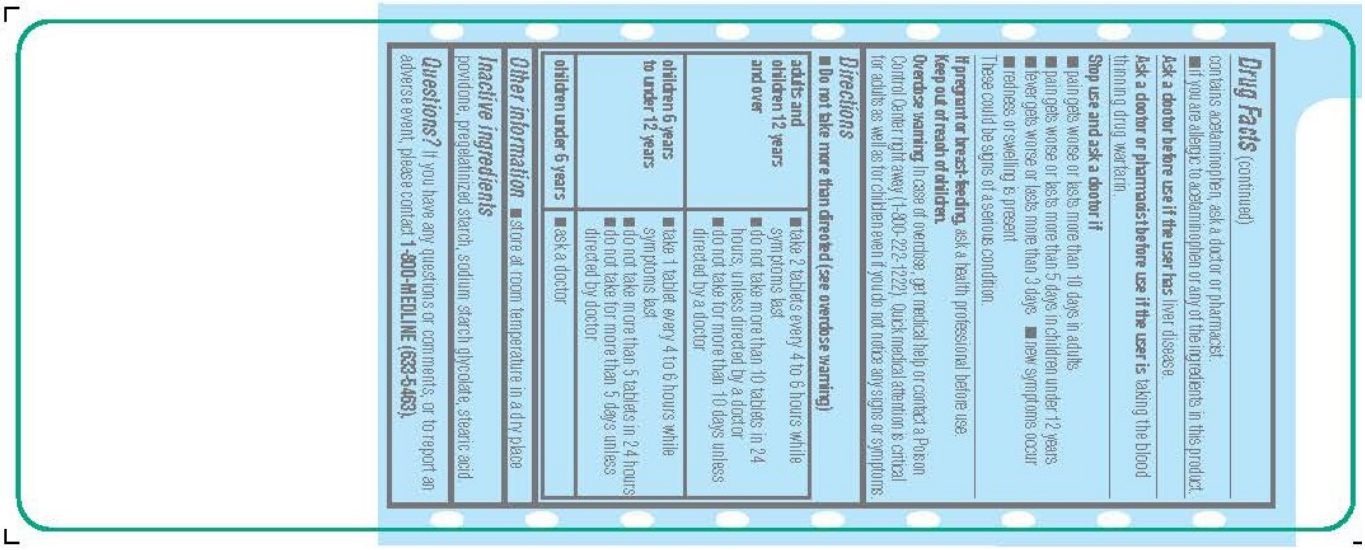
Regular Strength

Acetaminophen Tablets, 325 mg

+ Pain reliever

+ Fever reducer

1000 Tablets 325 mg each



MEDLINE ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53329-642
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
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND (ound flat faced beveled edge)	**Size**	12mm
Flavor		**Imprint Code**	GPI;A325;
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-642-30	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2013	
2	NDC:53329-642-98	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/26/2013	

Labeler - Medline Industries, Inc. (025460908)

Establishment

Name	Address	ID/FEI	Business Operations
Gemini Pharmaceuticals, Inc. dba Plus Pharma		055942270	manufacture(53329-642)

Revised: 12/2019 Medline Industries, Inc.