

REGULAR STRENGTH PAIN RELIEVER- acetaminophen tablet
Healthlife of USA

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.

Pain Reliever
Regular Strength

Drug Facts

Active Ingredient (In each tablet)

Acetaminophen 325mg

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
- temporarily reduces fever
- premenstrual and menstrual cramps

Warnings

Liver Warning:

ⓘ This product contains acetaminophen. The maximum daily dose of this product is 9 tablets (2925 mg) in 24 hours. Severe liver damage may occur if you take:

- more than 3000mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday while using this product

Allergy alert:

ⓘ Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs; stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or not 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 this product.

Ask doctor before use if you have

liver disease

Ask your 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 recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 of age and over:

- take 2 tablets every 4 to 6 hours while symptoms last
- do not take more than 9 tablets in 24 hours period
- do not use for more than 10 days unless directed by doctor

Children 6 to 12 years: take 1 tablet every 4 to 6 hours while symptoms last

- do not use more than 5 tablets in 24 hours period
- children under 6 years ask doctor.

Other Information

- store at controlled room temperature 20-25°C (68-77°F)
- read all product information before using
- **⚠TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch, Polyethylene Glycol, Polyvinyl Pyrolidone, Stearic acid, Talc, Titanium Dioxide.

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM-5PM EST or www.healthlifeofusa.com

Principal Display Panel**Regular Strength****Pain Reliever****Acetaminophen 325mg- Pain Reliever/ Fever Reducer****30 Tablets**



**Regular Strength
Pain Reliever**
Acetaminophen 325 mg
Pain Reliever / Fever Reducer
For Adults

**RETAIN CARTON FOR
COMPLETE DRUG FACTS**

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



**Regular Strength
Pain Reliever**
Acetaminophen 325 mg - Pain Reliever / Fever Reducer
For Adults

NDC 69517-123-030

Compare to
**REGULAR STRENGTH
Tylenol® active
ingredients***

Distributed by: HealthLife of USA LLC
Rahway, NJ 07065
www.healthlifeofusa.com



3 69517 12303 0

Lot. No.:

Exp. Date:

30 TABLETS

SEE NEW WARNINGS INFORMATION

Drug Facts (continued)

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Drug Facts (continued)

- Do not use**
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- If you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have liver disease
Ask your doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if:

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- fever gets worse or lasts more than 3 days
- new symptoms occur
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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 recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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REGULAR STRENGTH PAIN RELIEVER

acetaminophen tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69517-123

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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH 1500, PREGELATINIZED (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL340
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-123-30	30 in 1 BOTTLE; Type 0; Not a Combination Product	12/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/18/2017	

Labeler - Healthlife of USA (079656178)**Establishment**

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc.		037052099	manufacture(69517-123)

Revised: 12/2017

Healthlife of USA