

ACETAMINOPHEN - acetaminophen tablet
Physicians Total Care, 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 Tablets

*Compared to the active ingredient in Tylenol®

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Acetaminophen 325 mg

PURPOSES

Pain Reliever/Fever Reducer

USES

for the temporary relief of 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

- 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

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 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

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.

Keep out of reach of children.

OVERDOSAGE**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

Age	Dose
Adults and Children 12 years and over	<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
Children 6-11 years	<ul style="list-style-type: none">• 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	Do not use adult Regular Strength products in children under 6 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.

OTHER INFORMATION

- Store at room temperature 15°-30°C (59°-86°F)
- Use by expiration date on package.

INACTIVE INGREDIENTS

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid

Questions? To report a Serious Adverse Event contact 1-877-835-5472.

*This product is not manufactured or distributed by McNeil Consumer Products Co., owners of the registered trademark Tylenol®.

Distributed by:

Amneal Pharmaceuticals

104 Hippocrates Way,

Glasgow, KY 42141

Rev. 11/2009

Relabeling of "Additional Barcode Label" by:

Physicians Total Care, Inc.

Tulsa, OK 74146

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

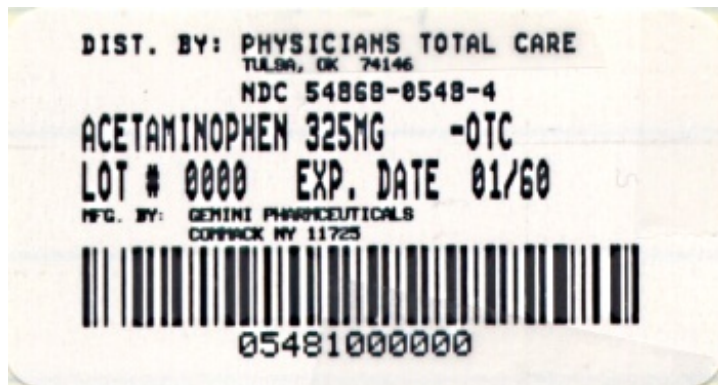
Acetaminophen Tablets

325 mg

Bottles of NDC 54868-
50 0548-2

Bottles of NDC 54868-
100 0548-4

Bottles of NDC 54868-
1000 0548-3



ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-0548(NDC:65162-350)
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	4mm
Flavor		Imprint Code	GPI;A325
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-0548-2	50 in 1 BOTTLE		
2	NDC:54868-0548-3	1000 in 1 BOTTLE		
3	NDC:54868-0548-4	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	10/24/2002	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 12/2009

Physicians Total Care, Inc.