

ACETAMINOPHEN- acetaminophen tablet
Richmond 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 325 mg

Active Ingredient

(in each tablet)

Acetaminophen 325 mg

Purpose

Pain Reliever / Fever Reducer

Uses

temporarily reduces fever and relieves minor aches and pains caused by

- common cold
- headache
- toothache
- backache
- muscular aches
- minor pain of arthritis
- premenstrual and menstrual cramps

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 tablets in 24 hours, which is the maximum daily amount
- 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 non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

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

- adult's pain gets worse or lasts more than 10 days
- child's pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use.

Overdose warning: Taking more than the recommended dose may cause liver damage. In case of

overdose contact Poison Control Center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs of symptoms.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

adults and children 12 years and over	2 tablets every 4 to 6 hours while symptoms last, not more than 10 tablets in 24 hours. Do not use more than 10 days unless directed by doctor
children 6 to 11 years	1 tablet every 4-6 hours while symptoms last, not more than 5 tablets in 24 hours. Do not use more than 5 days unless directed by doctor
children under 6 years	ask a doctor

Other Information

store at 15-30 °C (59-86 °F)

Inactive Ingredients

polyvinylpyrrolidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

Questions or Comments

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

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

PRINCIPAL DISPLAY PANEL

NDC- 54738-548-01... 100 APAP 325MG TABS

NDC 54738-548-01
*Compare to Active Ingredient in Regular Strength TYLENOL®

See New Warnings Information

REGULAR STRENGTH APAP
Acetaminophen USP, 325 mg
Pain Reliever/Fever Reducer
100 TABLETS

Richmond Pharmaceuticals, Inc.

Drug Facts
Active ingredient (in each tablet) Purpose
Acetaminophen 325 mg Pain reliever/Fever reducer

Uses
Temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- premenstrual and menstrual cramps
- toothache
- 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 for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if:

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- 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

Drug Facts continued on back of label

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

Richmond Pharmaceuticals, Inc. is not affiliated with the owner of the trademark regular strength TYLENOL®.
 Distributed by: Richmond Pharmaceuticals, Inc.
 Richmond, VA 23233, USA

Lot No.: LR1114
Exp. Date: 3

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PEEL HERE FOR INSIDE DRUG FACTS

Drug Facts (continued)
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: 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. 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 & 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
- 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
- do not use for more than 5 days unless directed by a doctor

children under 6 years: ■ ask a doctor

Other information
 Store at 15° to 30°C (59° to 86°F)

Inactive ingredients polyvinylpyrrolidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

Questions or comments? call 804-270-4498, 8:30 am - 4:30 pm ET, Monday - Friday

NDC- 54738-548-03... 1000 APAP 325MG TABS

NDC- 54738-548-50... 50 APAP 325MG TABS

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54738-548
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
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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	10mm
Flavor		Imprint Code	AP;012
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-548-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	
2	NDC:54738-548-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	
3	NDC:54738-548-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/01/2015	

Labeler - Richmond Pharmaceuticals, Inc. (043569607)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-548)

Revised: 10/2017

Richmond Pharmaceuticals, Inc.