

RUGBY REGULAR STRENGTH ACETAMINOPHEN- acetaminophen tablet

RUGBY LABORATORIES

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.

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
- 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 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

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 the reach of children.

Overdose warning:

In the 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	<ul style="list-style-type: none">• 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 use for more than 10 days unless directed by a doctor
children 6 to under 12 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• do not use for more than 5 days unless directed by a doctor

children under 6 years | ask a doctor

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients

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

Questions or comments?

1-800-645-2158

Rugby®

NDC 0536-1327-10

Compare to the active ingredients in Tylenol® Regular Strength

Regular Strength

Acetaminophen

325 mg

Pain Reliever/

Fever Reducer

1000 Tablets

Rugby® NDC 0536-1327-10
Compare to the active ingredient in Tylenol® Regular Strength*

Regular Strength Acetaminophen
325 mg

Pain Reliever/ Fever Reducer
1000 Tablets

PH 020 Actual Size

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN
TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each tablet)
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 ■ toothache ■ premenstrual and menstrual cramps ■ temporarily reduces fever

Warnings
Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 3,250 mg (10 tablets) for adults and 1,625 mg (5 tablets) for children. Serious liver damage may occur if you take 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 ■ you have liver disease ■ you are taking other medicines that may cause severe skin reactions. Symptoms may include: ■ skin redness ■ 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

Stop use and ask a doctor if ■ pain gets worse or lasts more than 10 days in adults ■ pain persists for more than 7 days in children ■ symptoms do not improve or get worse ■ 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 immediately. (1-800-422-4643) ■ Overdose 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 use for more than 10 days unless directed by a doctor
■ children 6 to 11 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
■ 12 years and over ■ take 2 tablets every 4 to 6 hours while symptoms last ■ do not use for more than 5 days unless directed by a doctor
children under 6 years ■ ask a doctor

Other information
■ store between 20-25°C (68-77°F)

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

Questions or comments? 1-800-645-2158

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., Mohale Consumer Healthcare Division, owner of the registered trademark Tylenol®.

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Distributed by:
RUGBY® LABORATORIES
Livonia, MI 48152
www.rugbylaboratories.com

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RUGBY REGULAR STRENGTH ACETAMINOPHEN			
acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1327

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 CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	PH020
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1327-06	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2021	
2	NDC:0536-1327-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2021	
3	NDC:0536-1327-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/11/2021	

Labeler - RUGBY LABORATORIES (079246066)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	analysis(0536-1327) , manufacture(0536-1327) , pack(0536-1327) , label(0536-1327)

Revised: 12/2022

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