

RUGBY 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.

Rugby Laboratories Acetaminophen Drug Facts

Active ingredient (in each tablet)

Acetaminophen 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

- adult takes more than 4,000 mg of acetaminophen 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 the user has ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if the user

- has liver disease
- is a child with pain of arthritis

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 (for adults) or 5 days (for children)
- 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	<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 • do not use for more than 10 days unless directed by a doctor
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 • do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Inactive ingredients

croscarmellose sodium*, povidone, pregelatinized starch, stearic acid

*may contain this ingredient

Questions or comments?

1-800-645-2158

Principal Display Panel

COMPARE TO ACTIVE INGREDIENT IN REGULAR STRENGTH TYLENOL®

REGULAR STRENGTH

Acetaminophen

WITHOUT ASPIRIN

PAIN RELIEVER/FEVER REDUCER

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

100 Acetaminophen

Tablets 325 mg Each

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Rugby[®]
NDC 0536-1164-01

COMPARE TO
ACTIVE INGREDIENT IN
REGULAR STRENGTH
TYLENOL[®] TM

REGULAR STRENGTH

Acetaminophen

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PAIN RELIEVER/FEVER REDUCER

DO NOT USE WITH OTHER
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**100 Acetaminophen
Tablets 325 mg Each**

Drug Facts (continued)

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Store at 20-25°C (68-77°F).

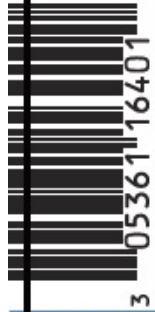
DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

**This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Regular Strength Tylenol[®].

Distributed by:

Rugby Laboratories
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www.rugbylaboratories.com
R-05 REV. 08/18
Re-Order No. 370584

: ADDS AT FL



PEEL BACK HERE

Drug Facts (continued)

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RUGBY ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1164
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND (beveled edge)	Size	10mm
Flavor		Imprint Code	325MG;L403
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1164-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/16/2019	

Labeler - Rugby Laboratories (079246066)