ACETAMINOPHEN EXTRA STRENGTH- acetaminophen capsule Family Dollar (FAMILY WELLNESS)

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 gelcap) Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - the common cold
 - backache
 - minor pain of arthritis
 - toothache
 - muscular aches
 - o premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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 you have

liver disease.

Ask a 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 the 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.

Direction

- do not take more than directed (see Overdose warning)
- do not take more than 6 gelcaps in any 24-hour period
- adults and children 12 years and over
 - o take 2 gelcaps every 6 hours while symptoms last
 - o do not take more than 10 days unless directed by a doctor
- children under 12 years: do not use

other information

- store between 15-30°C (59-86°F)
- avoid high humidity

Inactive ingredients

ammonium hydroxide, croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, purified water, shellac, silicon dioxide,

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9 AM-5 PM EST

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT OF TYLENOL® EXTRA STRENGTH RAPID RELEASE GELS†

EXTRA STRENGTH

Acetaminophen 500 mg

Pain Reliever/Fever Reducer

Adult

For Ages 12 Years and Over

RAPID RELEASE GELCAPS

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Extra Strength.Rapid Release Gels.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: MIDWOOD BRANDS, LLC 10611 MONROE RD, MATTHEWS, NC 28105

Product Label

product within 30 days to any Family Dollar store for NOT 100% SATISFIED? Return package and unused gelatin, hydroxypropyl cellulose, hypromellose, iron TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING. glycol, povidone, pregelatinized starch, propylene McNeil Consumer Healthcare, distributor of Tyleno Extra Strength Rapid Release Gels. hydroxide, croscarmellose sodium, D&C red #33 This product is not manufactured or distributed isopropyl alcohol, n-butyl alcohol, polyethylene FD&C blue #1,FD&C red #40, FD&C yellow #6, DISTRIBUTED BY: MIDWOOD BRANDS, LLC 10611 MONROE RD., MATTHEWS, NC 28105 oxide black, iron oxide red, iron oxide vellow, glycol, purified water, shellac, silicon dioxide store between 15-30°C (59-86°F) Questions or comments? a refund (with receipt) or exchange Monday-Friday 9AM-5PM EST Drug Facts (continued Inactive ingredients stearic acid, titanium dioxide Other information avoid high humidity Call 1-877-753-3935 if you are allergic to acetaminophen or any of the Ask a doctor before use if you have liver disease do not take more than directed (see Overdose PLD-A546A FC005078 ■ take 2 gelcaps every 6 hours while symptoms warning)

do not take more than 6 gelcaps in any 24-hour contact a Poison Control Center (1-800-222-1222 damage. In case of overdose, get medical help or right away. Quick medical attention is critical for Ask a doctor or pharmacist before use if you adults as well as for children even if you do not recommended dose (overdose) may cause liver pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days If pregnant or breast-feeding, ask a health are taking the blood thinning drug warfarin. These could be signs of a serious condition. Overdose warning: Taking more than the adults and children 12 years and over N inactive ingredients in this product 25 redness or swelling is present Keep out of reach of children. SKU 913884 **Drug Facts** (continued Stop use and ask a doctor if notice any signs or symptoms. new symptoms occur professional before use 1978 period ast Purpose fever reducer Pain reliever, 3 or more alcoholic drinks every day while using acetaminophen. Severe liver damage may occur if Ises = temporarily relieves minor aches and Allergy alert: Acetaminophen may cause severe with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, minor pain of arthritis with other drugs containing acetaminopher more than 4,000 mg of acetaminophen in if a skin reaction occurs, stop use and seel muscular aches premenstrual and menstrual cramps ■ skin reddening
■ blisters
■ rash skin reactions. Symptoms may include: Liver warning: This product contains ■ the common cold ■ headache temporarily reduces fever medical help right away. Active ingredient Acetaminophen 500 mg in each gelcap) **Drug Facts** backache toothache this product pains due to: 24 hours Do not use you take: FAMILY Wel COMPARE TO THE ACTIVE INGREDIENT OF TYLENOL® Extra strength rapid release gels† NDC 55319-541-50 **EXTRA STRENGTH** Acetaminophen 500 mg Pain Reliever/Fever Reducer Adult

ammonium

Exp. Date

Lot No.:

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

do not take more than 10 days unless directed

■ children under 12 years: do not use

by a doctor

ask a doctor or pharmacist.

RAPID RELEASE GELCAPS

ACTUAL SIZE

For Ages 12 Years and Over

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen capsule

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-541

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 500 mg

Inactive Ingredients

mactive ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SHELLAC (UNII: 46N107B710)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	red, gray, blue	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	G1G1
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55319-541- 50	1 in 1 BOX	07/31/2018	04/26/2024	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
art343	07/31/2018	04/26/2024		
	Citation	Citation Date		

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 10/2021 Family Dollar (FAMILY WELLNESS)