ARTHRITIS PAIN RELIEVER EXTENDED RELEASE- acetaminophen tablet P & L Development, LLC

Drug Facts

Active ingredient (in each caplet)
Acetaminophen USP,650 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

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

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks ever 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 a 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: 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.

Directions

- do not take more than directed (see Overdose warning)
- adults
 - take 2 caplets every 8 hours with water
 - o swallow whole; do not crush, chew, split or dissolve
 - do not take more than 6 caplets in 24 hours
 - o do not use for more than 10 days unless directed by a doctor
- under 18 years of age: ask a doctor

Other information

store between 20-25°C (68-77°F)

Inactive ingredients

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

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

Principal Display Panel

Compare to the active ingredient in **Tylenol® 8HR Arthritis Pain**†

see new warning

arthritis pain reliever

acetaminophen extended-release tablets USP, 650 mg

pain reliever/fever reducer

- for the temporary relief of minor arthritis pain
- contains no aspirin

caplets*

(*capsule-shaped bi-layer tablets)

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8 HR Arthritis Pain.

TAMPER EVIDENT: DO NOT USE IF FOIL INNER SEAL IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Product Label

Exp. Date:

Lot No.:

PLD-A683A

FC007025

59 Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590 726 01 310 9

Orug Facts (continued)

Ask a doctor before use if you have liver

Purpose

Active ingredient

ready incase

Drug Facts

(in each caplet)

Pain reliever/

fever reducer

Acetaminophen USP, 650 mg.

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

redness or swelling is present new symptoms occur

These could be signs of a serious condition.

the common cold

temporarily reduces fever

neadache

■ toothache

■ minor pain of arthritis
■ backache premenstrual and menstrual cramps

due to

muscular aches

medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical If pregnant or breast-feeding, ask a health Overdose warning: In case of overdose, get attention is critical for adults as well as for Keep out of reach of children. professional before use.

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Directions

do not take more than directed (see Overdose warning)

adults

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

using this product

■ skin reddening
■ blisters
■ rash
If a skin reaction occurs, stop use and seek

medical help right away

Do not use

 with other drugs containing acetaminophen 3 or more alcoholic drinks every day while

maximum daily amount

swallow whole; do not crush, chew, split, or take 2 caplets every 8 hours with water

do not take more than 6 caplets in 24 hours do not use for more than 10 days unless

directed by a doctor

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF FOIL INNER SEAL IS BROKEN OR MISSING.

If you are allergic to acetaminophen or any of the inactive ingredients in this product

acetaminophen, ask a doctor or pharmacist prescription or nonprescription). If you are

not sure whether a drug contains

Orug Facts (continued)

povidone, pregelatinized starch, sodium starch cellulose, hypromellose, magnesium stearate microcrystalline cellulose, polyethylene glyco Inactive ingredients hydroxyethyl glycolate, stearic acid

1-877-753-3935 Monday-Friday 9AM-5PM EST Questions or comments?

McNeil Consumer Healthcare, distributor of Tylenol® This product is not manufactured or distributed by 8 HR Arthritis Pain.

under 18 years of age: ask a doctor dissolve

with any other drug containing acetaminophen

Other information

store between 20-25°C (68-77°F)

Compare to the active ingredient in Tylenol® 8 HR Arthritis Pain† NDC 59726-013-10

temporarily relieves minor aches and pains

see new warning arthritis pain

acetaminophen extended-release tablets USP, 650 mg pain reliever/fever reducer

contains no aspirin

relief of minor arthritis pain

for the temporary

100 caplets* 650 mg each (*capsule-shaped bi-layer tablets)

not actual size



READYinCASE Arthritis Pain Reliever

ARTHRITIS PAIN RELIEVER EXTENDED RELEASE

acetaminophen tablet

Product	Inform	ation
Product	11110111	lation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59726-013

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TAL (UNIT 20200ITLOD) (ACETAMINODUEN LINU 20200ITLOD)	ACETANAINIODUENI	CEO

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 650 mg

Inactive Ingredients

mactive myredients	
Ingredient Name	Strength
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G650
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726- 013-10	1 in 1 BOX	04/30/2020	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	04/30/2020	

Labeler - P & L Development, LLC (800014821)

Revised: 3/2023 P & L Development, LLC