

ACETAMINOPHEN EXTENDED RELEASE- acetaminophen tablet
United Natural Foods, Inc. dba UNFI

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 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 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
 - swallow whole; do not crush, chew, split or dissolve
 - do not take more than 6 caplets in 24 hours
 - 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

D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hydroxyethyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose povidone, pregelatinized starch, sodium lauryl sulfate

Questions or comments?

Call toll free **1-877-932-7948**

Principal Display Panel

compare Tylenol® 8HR Arthritis Pain active ingredient†

extended-release

arthritis pain reliever

acetaminophen 650 mg

pain reliever/fever reducer

for the temporary relief of minor arthritis pain

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 PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

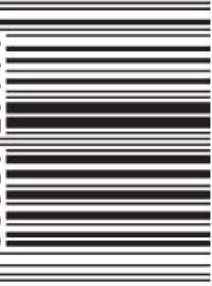
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: SUPERVALU INC., EDEN PRAIRIE, MN 55344 USA

Product Label

Exp. Date:
Lot No.:

7 0 41163 40992



PLD-B495A FC006611

Drug Facts

Active ingredient (in each caplet) **Purpose**

Acetaminophen 650 mg..... Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to
 - minor pain of arthritis
 - muscular aches
 - premenstrual and menstrual cramps
 - headache
- 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 every day while using this product

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

- skin reddening
- skin itching
- 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.

Drug Facts (continued)

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
 - swallow whole; do not crush, chew, split or dissolve
 - do not take more than 6 caplets in 24 hours
 - do not use for more than 10 days unless directed by a doctor
- under 18 years of age:** ask a doctor

Drug Facts (continued)

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients

D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hydroxyethyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose, povidone, pregelatinized starch, sodium lauryl sulfate

Questions or comments?

Call toll free 1-855-423-2630

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

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 UNFI, PROVIDENCE, RI 02908 USA

Like it or let us make it right.
That's our quality promise.
855-423-2630



EQUALINE®

extended-release

arthritis pain reliever

acetaminophen 650 mg

pain reliever/fever reducer

for the temporary relief of minor arthritis pain

50 caplets* (*capsule-shaped bi-layer tablets)

compare to Tylenol®
8 HR Arthritis Pain
active ingredient†
NDC 41163-669-50



actual size

EQUALINE Extended Release Arthritis pain Reliever

ACETAMINOPHEN EXTENDED RELEASE

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-669
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	511
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-669-50	1 in 1 BOX	09/30/2019	12/31/2024
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:41163-669-10	1 in 1 BOX	09/30/2019	12/31/2024
2		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	ANDA207035	09/30/2019	12/31/2024

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Revised: 6/2024

United Natural Foods, Inc. dba UNFI