

ACETAMINOPHEN EXTENDED RELEASE- acetaminophen tablet EQUALINE (SuperValu)

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.:



PLD-B495A F0006611

Drug Facts	Purpose
Active ingredient (in each caplet)	Pain reliever/ fever reducer
Acetaminophen 650 mg.....	
Uses	
<ul style="list-style-type: none"> temporarily relieves minor aches and pains due to <ul style="list-style-type: none"> minor pain of arthritis muscular aches premenstrual and menstrual cramps headache temporarily reduces fever 	<ul style="list-style-type: none"> backache toothache the common cold
Warnings	
<p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> 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 <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> skin reddening skin itching blisters rash <p>If a skin reaction occurs, stop use and seek medical help right away.</p>	
Do not use	
<ul style="list-style-type: none"> 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)	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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 <p>These could be signs of a serious condition.</p>	
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 (see Overdose warning)	
adults	<ul style="list-style-type: none"> do not take more than directed 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	<ul style="list-style-type: none"> 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.

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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®

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

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)



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	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:41163-669-10	1 in 1 BOX	09/30/2019	
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	

Labeler - EQUALINE (SuperValu) (006961411)

Revised: 11/2022

EQUALINE (SuperValu)