

8 HOUR ARTHRITIS PAIN- acetaminophen tablet, extended release
CHAIN DRUG MARKETING ASSOCIATION, INC.

1200A-QCH-2024-0613

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
 - muscular aches
 - backache
 - premenstrual and menstrual cramps
 - the common cold
 - headache
 - toothache
- 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
- 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 haveliver disease

Ask a doctor or pharmacist before use if you aretaking 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 (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	<ul style="list-style-type: none">▪ 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, unless directed by a doctor▪ do not use for more than 10 days unless directed by a doctor
under 18 years of age	<ul style="list-style-type: none">▪ ask a doctor

Other information

- store between 20-25°C (68-77°F)
- retain carton for complete product information and warnings

Inactive ingredients

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose,

polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

PRINCIPAL DISPLAY PANEL

QUALITY CHOICE®

NDC 83324-083-50

†Compare to Active Ingredient in **TYLENOL® 8HR Arthritis Pain**

8 Hour Arthritis Pain

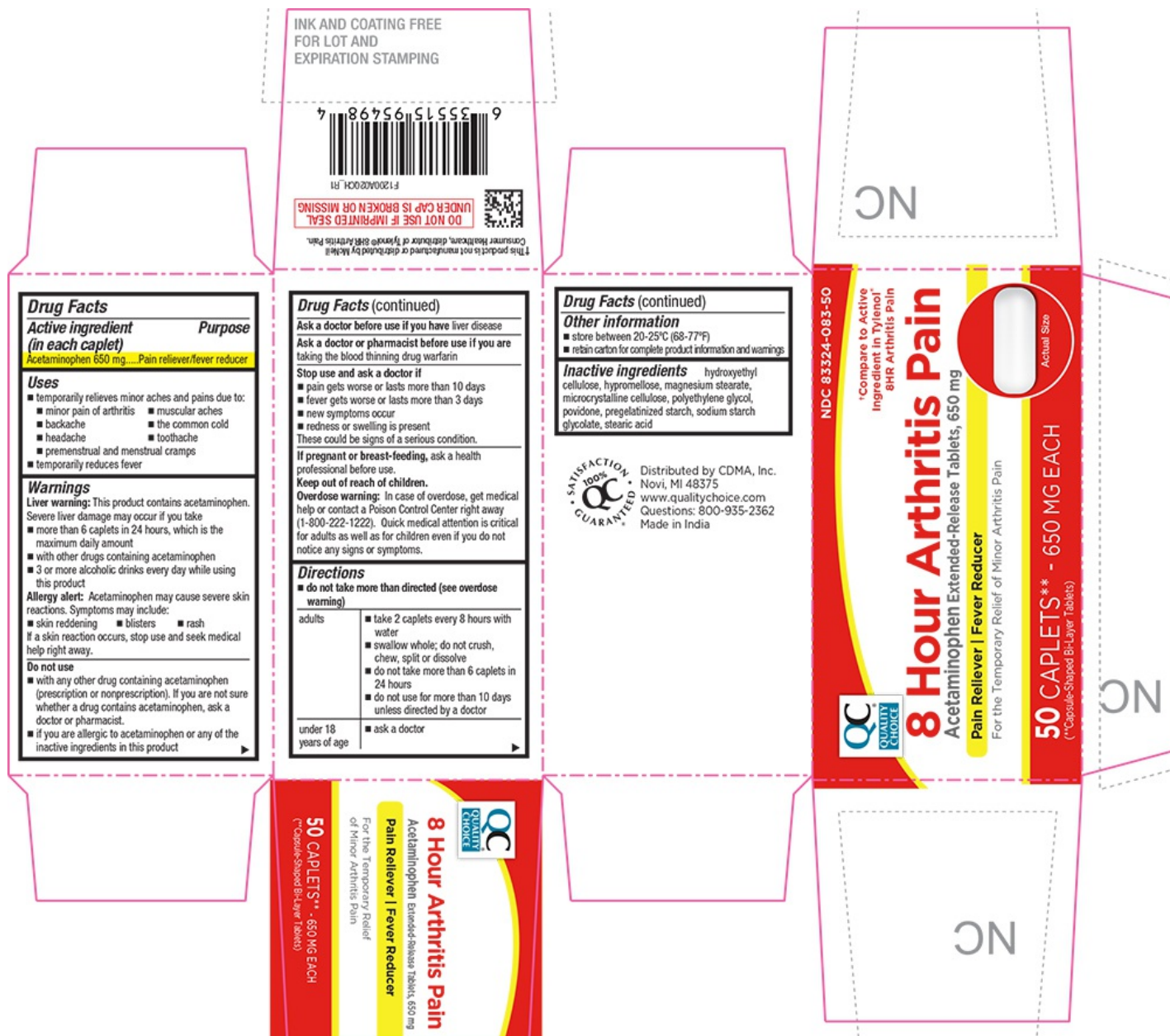
Acetaminophen Extended-Release Tablets, 650 mg

Pain Reliever | Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

50 CAPLETS** - 650 MG EACH

(**Capsule-Shaped Bi-Layer Tablets)



8 HOUR ARTHRITIS PAIN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-083
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
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-083-50	1 in 1 CARTON	05/01/2024	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:83324-083-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	05/01/2024	

Labeler - CHAIN DRUG MARKETING ASSOCIATION, INC. (011920774)