ACETAMINOPHEN- acetaminophen tablet, extended release
CHAIN DRUG MARKETING ASSOCIATION INC

QCH-1200A-2020-0828

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 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 (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	▪ 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	▪ 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

NDC 63863-660-50

QUALITY CHOICE®

†Compare to the Active Ingredient of Tylenol® 8HR Arthritis Pain

8 Hour Arthritis Pain

Acetaminophen Extended-Release Tablets, 650 mg

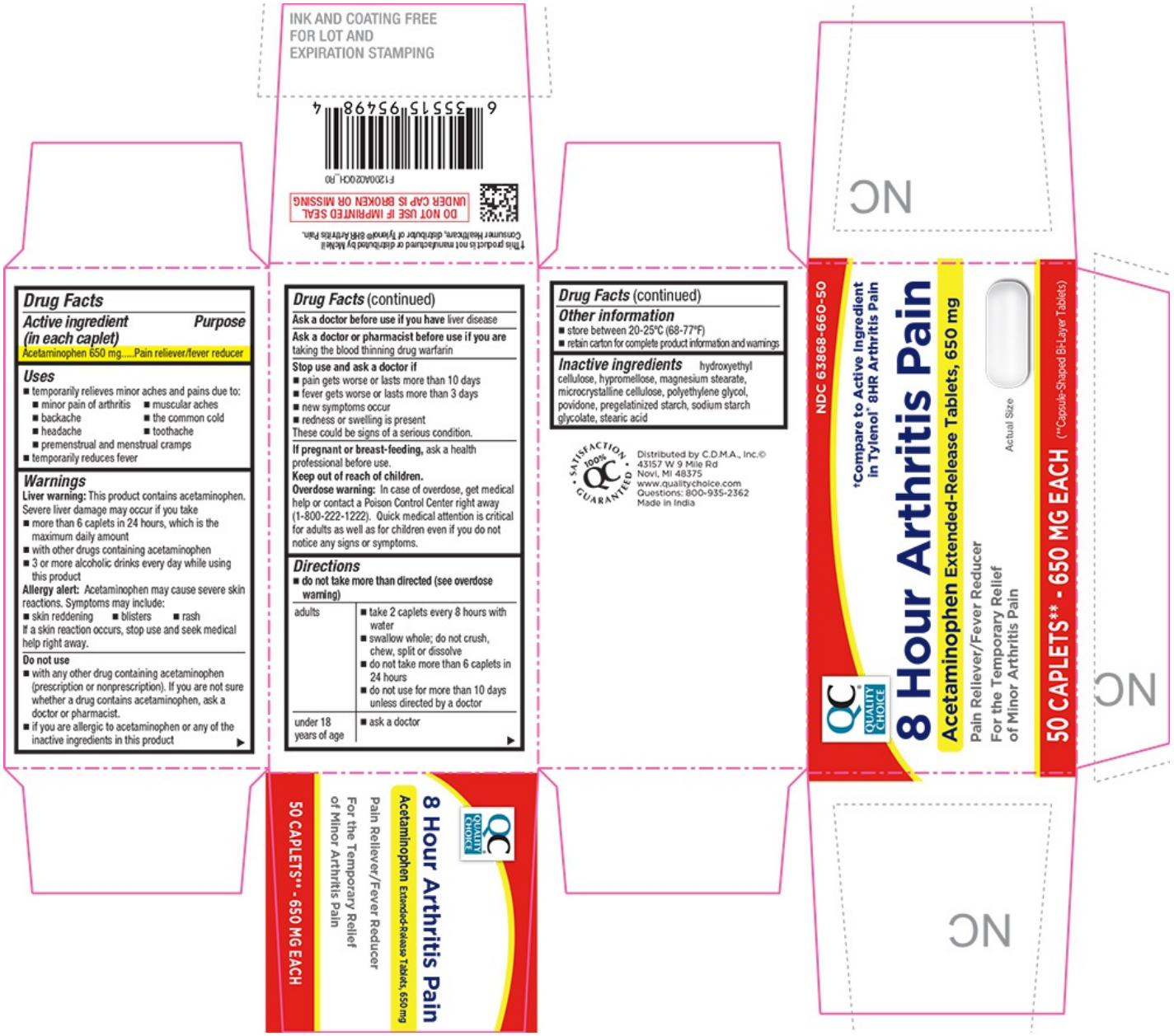
Pain Reliever/Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

Actual Size

50 CAPLETS** - 650 MG EACH

(**Capsule-Shaped Bi-Layer Tablets)



ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-660
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:63868-660-50	1 in 1 PACKAGE	08/01/2020	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63868-660-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	
3	NDC:63868-660-22	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	08/01/2020	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Revised: 12/2022 CHAIN DRUG MARKETING ASSOCIATION INC