ARTHRITIS PAIN RELIEF- acetaminophen tablet, film coated, extended release
Publix Super Markets Inc

Publix Super Markets, Inc. Arthritis Pain Relief 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 • do not use for more than 10 days unless directed by a doctor
under 18 years of age	• ask a doctor

Other information

- store at 68-77°F (20-25°C)
- **do not use if printed foil under cap is broken or missing**

- meets the requirements of USP *Dissolution Test 4*

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

Principal Display Panel

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arthritis pain relief

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg

Pain reliever/fever reducer

• For the temporary relief of minor arthritis pain

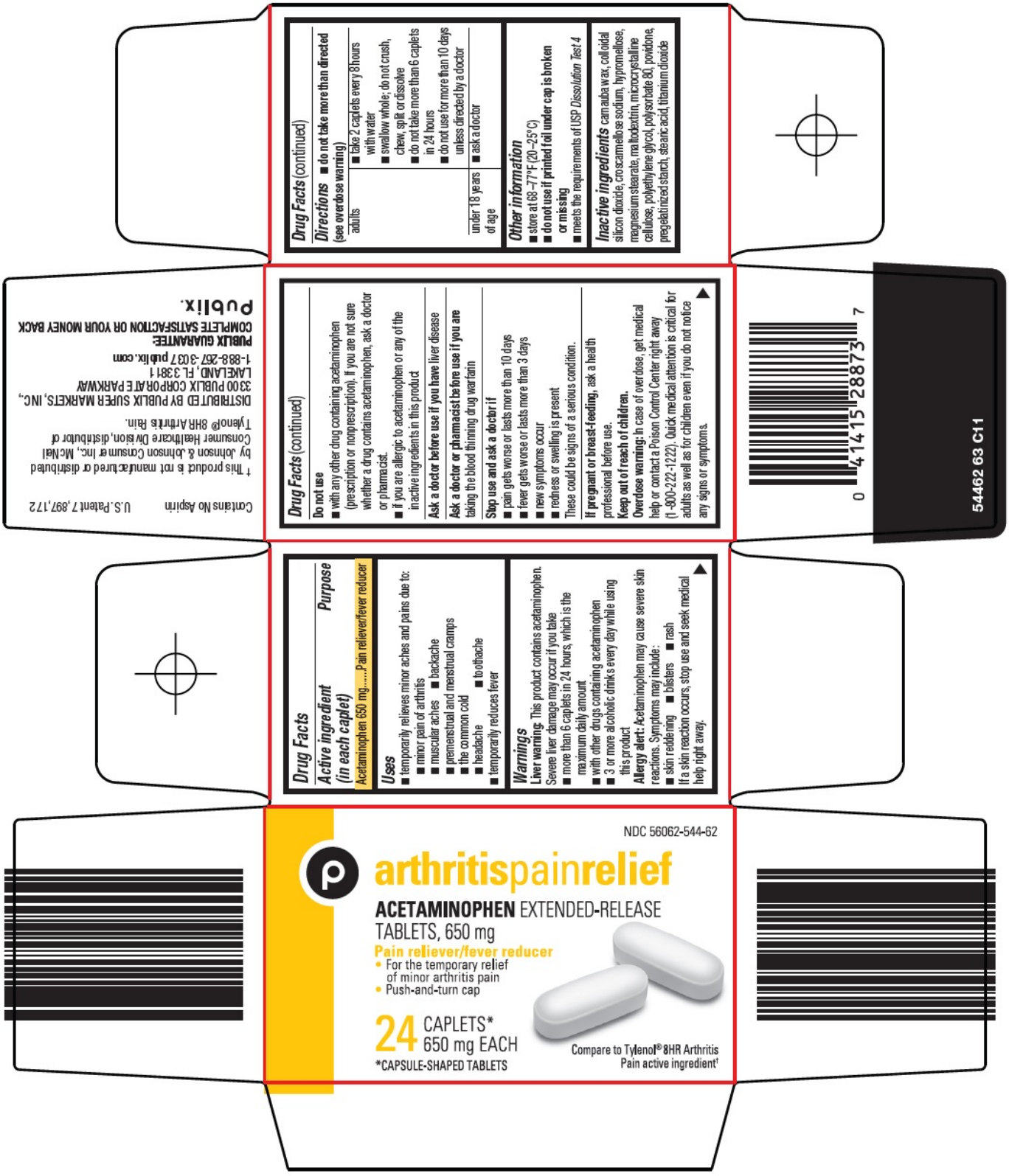
• Push-and-turn cap

24 CAPLETS*

650 mg EACH

*CAPSULE-SHAPED TABLETS

Compare to Tylenol® 8HR Arthritis Pain active ingredient



ARTHRITIS PAIN RELIEF

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56062-544
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	L544
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-544-62	1 in 1 CARTON	11/26/2007	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:56062-544-78	1 in 1 CARTON	11/28/2007	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	11/26/2007	

Labeler - Publix Super Markets Inc (006922009)

Revised: 5/2025

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