8HR ARTHRITIS PAIN RELIEF- acetaminophen tablet, extended release Major Pharmaceuticals

Major Acetaminophen Extended Release Tablets 650 mg

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 ifyou 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

	 take 2 caplets every 8 hours with water
	 swallow whole; do not crush, chew, split, or dissolve
adults	 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)
- The FDA approved dissolution methods differ from USP

Inactive ingredients carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments? Call 1-877-290-4008



If a skin reaction occurs, stop use and seek medical help right away

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Inside

5.3125 in

Pain reliever/fever reduce

Purpose

8hr arthritis pain relief

NDC 0904-7561-60

acetaminophen extended-release tablets USP, 650 mg

Contains No Aspirin

STOP PEELING

Adhesive Area

MAJOR

Questions or comments? Call 1-877-290-4008

povidone, pregelatinized starch, sodium starch glycolate, titanium

nypromellose, magnesium stearate, microcrystalline cellulose

nactive ingredients camauba wax, hydroxyethyl cellulose

Other information under 18 years of age

The FDA approved dissolution methods differ from USP

ask a doctor

pain reliever/fever reducer

for the temporary relief of minor arthritis pain

100 caplets*

actual size

(*capsule-shaped bi-layer tablets)

BROKEN OR MISS

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMIN OPHE

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temporarily relieves minor aches and pains due to:

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nremenstrual and menstrual cramps the common cold

■ toothache

headache

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Allergy alert: acetaminophen may cause severe skin reactions. Symptoms 3 or more alcoholic drinks every day while using this product skin reddening include:

*This product is not manufactured or distributed by k trademark Tylenol® 8m Arthritis Pain 699R Distributed by: MAJOR® PHARMACEUTICALS indianapolis, IN 46268 (800) 616-2471 Drug Facts (

owner of the registered

ape

under

blisters continued

> EXP.: LOT:

Made in India 3

.major-rugby.com



Varnish Omit Area

Outside

8HR ARTHRITIS PAIN RELIEF

acetaminophen tablet, extended release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0904-7561

ORAL **Route of Administration**

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)

ACETAMINOPHEN

650 mg

Inactive Ingredients		
Ingredient Name	Strength	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
POVIDONE (UNII: FZ 989GH94E)		
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)		
TRIACETIN (UNII: XHX3C3X673)		
STARCH, CORN (UNII: O8232NY3SJ)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		

Product Characteristics			
Color	white ((White to off-white))	Score	no score
Shape	OVAL (Capsule-shaped tablet)	Size	19mm
Flavor		Imprint Code	71
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:0904-7561- 60	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215486	05/06/2025	

Labeler - Major Pharmaceuticals (191427277)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment					
Name	Address	ID/FEI	Business Operations		
MARKSANS PHARMA LIMITED		925822975	manufacture(0904-7561)		

Revised: 5/2025 Major Pharmaceuticals