ACETAMINOPHEN- acetaminophen tablet, extended release
Granules Pharmaceuticals Inc.

Acetaminophen Extended Release Tablets 650 mg

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen USP, 650 mg

PURPOSE

Pain reliever/fever reducer

USES

For **Arthritis Pain label**
- 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

For **Muscle Aches & Pain label**
- temporarily relieves minor aches and pains due to:
  - muscular aches
  - backache
  - minor pain of arthritis
  - 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 everyday 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 drugs 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 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

For Arthritis Pain Label
• **do not take more than directed (see overdose warning)**

	• take 2 caplets every 8 hours with water

adults	• 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

For Muscle Ache and Pain label
• do not take more than directed (see overdose warning)

adults and children 12 years of age and over	• 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
children under 12 years	• do not use

OTHER INFORMATION

• store between 20-25°C (68-77°F)
• do not use if foil inner seal is broken or missing.

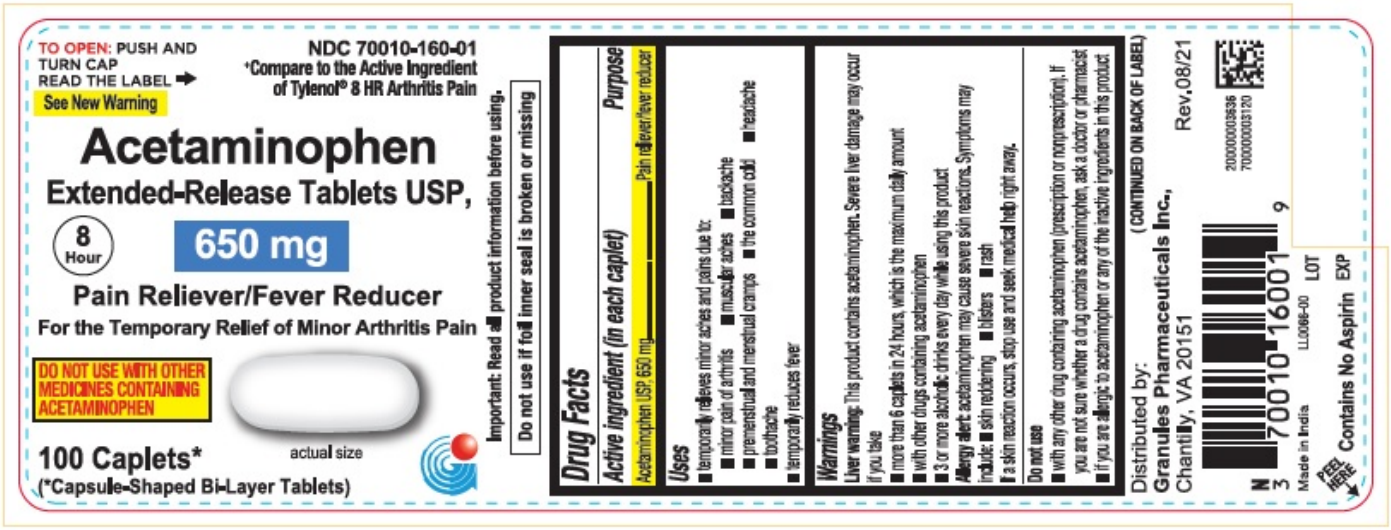
INACTIVE INGREDIENTS

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

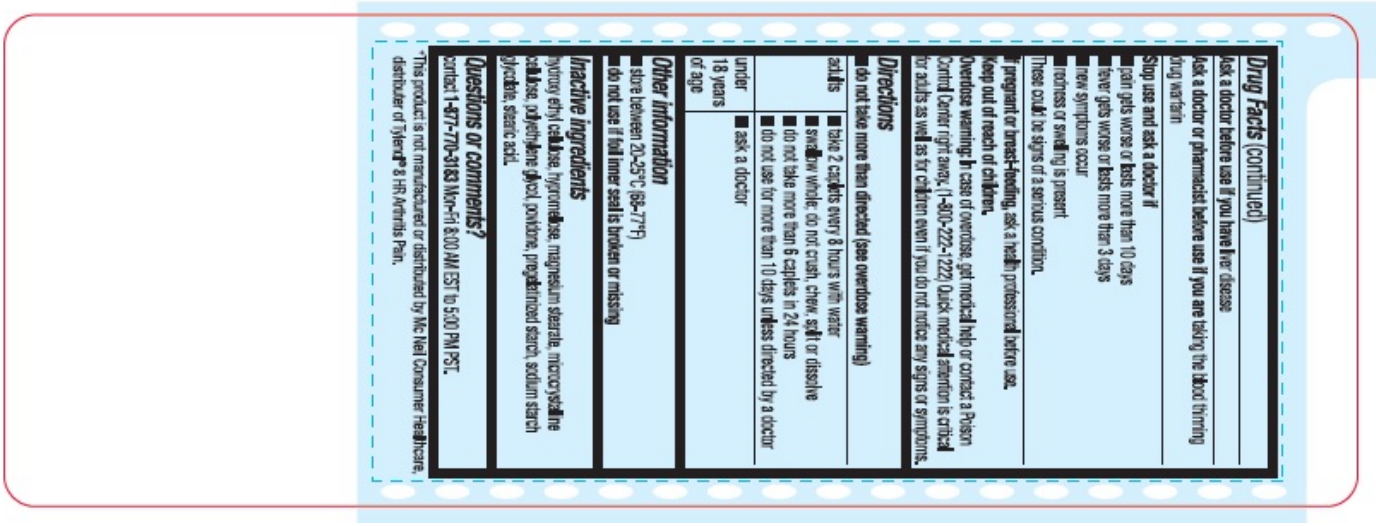
QUESTIONS OR COMMENTS ?

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

PRINCIPAL DISPLAY PANEL



Inside (adhesive side)



ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70010-160
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**

HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

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:70010-160-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	02/15/2022	

Labeler - Granules Pharmaceuticals Inc. (079825711)

Registrant - Granules India Limited (915000087)

Revised: 1/2023 Granules Pharmaceuticals Inc.