

ACETAMINOPHEN- acetaminophen tablet extended release tablet, extended release

Bryant Ranch Prepack

Timely 699R 704R Acetaminophen Extended-Release Tablets USP, 650 mg

Active ingredient (in each caplet)

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

For Arthritis Pain

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 & Pains

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 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 using 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

For Arthritis Pain

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

For Muscle Aches & Pains

Do not take more than directed. See overdose warning

adults and children 12 years 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)
- 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**

HOW SUPPLIED

Acetaminophen Extended-Release 650 mg Tablet

- NDC 71335-9746-1: 30 Tablets in a BOTTLE
- NDC 71335-9746-2: 100 Tablets in a BOTTLE
- NDC 71335-9746-3: 50 Tablets in a BOTTLE
- NDC 71335-9746-4: 60 Tablets in a BOTTLE
- NDC 71335-9746-5: 120 Tablets in a BOTTLE
- NDC 71335-9746-6: 19 Tablets in a BOTTLE
- NDC 71335-9746-7: 20 Tablets in a BOTTLE

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Acetaminophen Extended-Release 650 mg Tablet



GTIN 00371335974619
Lot 208620
Exp 7/10/2025
SN 0123456789

Each tablet contains: Acetaminophen, USP
650 mg

Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) (see USP controlled Room Temperature).

Dispense in a tight, light-resistant container.
Keep tightly closed.

Do not use with other medicines containing acetaminophen.

Keep this and all drugs out of the reach of children.

NDC 71335-9746-1

Acetaminophen Extended-Release Tablets, USP

650 mg

30 Tablets



Repackaged by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Marksans Pharma
Limited



ACETAMINOPHEN

acetaminophen tablet extended release tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71335-9746(NDC:49483-699)
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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	

Product Characteristics

Color	white (White to off white)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-9746-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2023	
2	NDC:71335-9746-2	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2024	
3	NDC:71335-9746-3	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2024	
4	NDC:71335-9746-4	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2024	
5	NDC:71335-9746-5	120 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2024	
6	NDC:71335-9746-6	19 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2024	
7	NDC:71335-9746-7	20 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215486	10/04/2021	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-9746) , RELABEL(71335-9746)

Revised: 4/2024

Bryant Ranch Prepack