

**ACETAMINOPHEN- acetaminophen tablet, extended release
Granules India Limited**

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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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

Acetaminophen Extended Release Tablets USP, 650 mg

Each Extended Release tablet contains
Acetaminophen USP 650 mg

Batch No. : XXXXXXX
Mfg.Dt. : MM/YYYY
Exp.Dt. : MM/YYYY
NDC No. : 62207-183-97
Mfg.Lic.No. : 37/RR/AP/2003/F/R

Pack Size : 30 Kg
Gross Wt. : 00.000 Kg
Tare Wt. : 00.000 Kg
Net Wt. : 00.000 Kg
Drum No. : 000

Storage : Store between 20 - 25 °C (68 - 77 °F)

Caution : For repacking only.

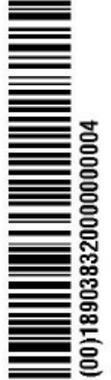


(01)50362207183975(17)000000(10)XXXXXXX

Sujani
Pillapalem
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Digitally signed
by Sujani
Pillapalem
Date:
2021.04.23
13:58:11 +05'30'

Country of Origin: INDIA



(00)189038320000000004

FG code : 700000002537

Acetaminophen Extended Release Tablets USP, 650 mg

Each Extended Release tablet contains
Acetaminophen USP 650 mg

Batch No. : XXXXXXX
Mfg.Dt. : YYYY/MM
Exp.Dt. : YYYY/MM
NDC No. : 62207-183-35
Mfg.Lic.No. : 37/RR/AP/2003/F/R

No. of Units : 3000

Storage : Store between 20 - 25 °C (68 - 77 °F)

Caution : For repacking only.

Country of Origin: INDIA

FG Code: 700000003316

Acetaminophen Extended Release Tablets USP, 650 mg

Each Extended Release tablet contains
Acetaminophen USP 650 mg

Batch No. : XXXXXXX
Mfg.Dt. : MM/YYYY
Exp.Dt. : MM/YYYY
NDC No. : 62207-183-34
Mfg.Lic.No. : 37/RR/AP/2003/F/R

No. of Units : 5 x 3000
Gross Wt. : 00.000 Kg
Tare Wt. : 00.000 Kg
Net Wt. : 00.000 Kg
Box number : 000

Storage : Store between 20 - 25 °C (68 - 77 °F)

Caution : For repacking only.



(01)50362207183340(17)000000(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

Product code : 70000001368

Activ

NOT FOR RETAIL SALE

READ THE LABEL
See New Warning

DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN

NDC 62207-183-49

*Compare to the active ingredient of Tylenol® 8 HR
Arthritis Pain

ARTHRITIS PAIN

Acetaminophen
Extended-release
tablets USP, 650 mg
Pain Reliever / Fever Reducer

For The Temporary Relief Of Minor
Arthritis Pain



8HR

1000 Caplets*
650 mg each

*Capsule-Shaped Bi-Layer Tablets

Drug Facts

Active ingredient (in each caplet)

Acetaminophen USP, 650 mg..... 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 redness ■ 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



MADE IN INDIA
M. L. No.: 37/RR/AP/2003/F/R

Manufactured By:
Granules India Limited
Hyderabad – 500 081, INDIA

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

LOT:
EXP:



Drug Facts (continued)

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

Other information

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

Inactive Ingredients

hydroxy ethyl 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.

Contains No Aspirin

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8 HR Arthritis Pain.

TO OPEN: PUSH AND TURN CAP
READ THE LABEL

DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN

NDC 62207-183-51

*Compare to the active ingredient of Tylenol® 8 HR
Arthritis Pain

ARTHRITIS PAIN

Acetaminophen
Extended-release
tablets USP, 650 mg
Pain Reliever / Fever Reducer

For The Temporary Relief Of Minor
Arthritis Pain



8HR

10 Caplets*
650 mg each

*Capsule-Shaped Bi-Layer Tablets

Drug Facts

Active ingredient (in each caplet)

Acetaminophen USP, 650 mg..... Pain reliever/fever reducer

Purpose

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



MADE IN INDIA

M. L. No.: 37/RR/AP/2003/F/R
XXXXXXXXXXXX

Manufactured By:
Granules India Limited
Hyderabad – 500 081, INDIA

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

LOT:
EXP:



EXP:
LOT:

NDC 62207-188-51 See New Warning

*Compare to the active ingredient of Tyleno® 8 HR Muscle Aches & Pain

MUSCLE ACHES & PAIN

**Acetaminophen
Extended-release
tablets USP, 650 mg**

Pain Reliever / Fever Reducer

**For Up to 8 Hours Relief of Minor
Muscle Aches & Pain**

**10 Caplets*
650 mg each**

*Capsule-Shaped Bi-Layer Tablets

Drug Facts

Active ingredient (in each caplet) Acetaminophen USP, 650 mg	Purpose Pain relief/ fever reducer
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Uses

- 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, or 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

Drug Facts (continued)

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 and children 12 years of age and over	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> do not use

Other information

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

Drug Facts (continued)

Inactive Ingredients
hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregeatinized 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.

Contains No Aspirin

* This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tyleno® 8 HR Muscle Aches & Pain.



MADE IN INDIA

M. L. No.: 37/RR/AP/2003/F/R
XXXXXXXXXXXX

Manufactured By:
Granules India Limited
Hyderabad – 500 081, INDIA

Distributed By:
Granules USA, Inc.
Parsippany, NJ 07054

Labeling Form at Information

Form at	Description
Front Side	Front Side
Back Side	Back Side
Top Panel	Top Panel
Bottom Panel	Bottom Panel
Right Panel	Right Panel
Left Panel	Left Panel
Side Panel	Side Panel
End Panel	End Panel
Header	Header
Footer	Footer

Acetaminophen Extended Release Tablets USP, 650 mg

Each Extended Release tablet contains
Acetaminophen USP 650 mg

Batch No. : XXXXXXX

No. of Units : 3000

Mfg.Dt. : MM/YYYY

Exp.Dt. : MM/YYYY

NDC No. : 62207-183-87

Mfg.Lic.No. : 37/RR/AP/2003/F/R

Storage : Store between 20 - 25 °C (68 - 77 °F)

Caution : For repacking only.

Country of Origin: INDIA

Product code : 700000001368

Go to

NOT FOR RETAIL SALE

READ THE LABEL

See New Warning

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

NDC 62207-188-49

*Compare to the active ingredient of Tylenol® 8 HR Muscle Aches & Pain

MUSCLE ACHES & PAIN

Acetaminophen Extended-release tablets USP, 650 mg Pain Reliever / Fever Reducer

For Up to 8 Hours Relief of Minor Muscle Aches & Pain



8HR

1000 Caplets* 650 mg each

*Capsule-Shaped Bi-Layer Tablets

Drug Facts

Purpose Active ingredient (in each caplet) Acetaminophen USP, 650 mg..... Pain reliever /fever reducer

Uses 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 redness 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 non prescription). 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



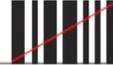
MADE IN INDIA

M. L. No.: 37/RR/AP/2003/F/R

Manufactured By: Granules India Limited Hyderabad - 500 081, INDIA

Distributed By: Granules USA, Inc. Parsippany, NJ 07054

LOT: EXP:



Drug Facts (continued)

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

Other information

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

Inactive ingredients

hydroxy ethyl 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.

Contains No Aspirin

*This product is not manufactured or distributed by Mc Neil Consumer Healthcare, distributor of Tylenol® 8 HR Muscle Aches & Pain

TO OPEN: PUSH AND TURN CAP READ THE LABEL

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

NDC 62207-188-51

*Compare to the active ingredient of Tylenol® 8 HR Muscle Aches & Pain

MUSCLE ACHES & PAIN

Acetaminophen Extended-release tablets USP, 650 mg Pain Reliever / Fever Reducer

For Up to 8 Hours Relief of Minor Muscle Aches & Pain



8HR

10 Caplets* 650 mg each

*Capsule-Shaped Bi-Layer Tablets

Drug Facts

Active ingredient (in each caplet) Acetaminophen USP, 650 mg..... Pain reliever/fever reducer

Purpose

Uses 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

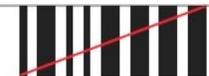


MADE IN INDIA

M. L. No.: 37/RR/AP/2003/F/R XXXXXXXXXXXXX

Manufactured By: Granules India Limited Hyderabad - 500 081, INDIA

Distributed By: Granules USA, Inc. Parsippany, NJ 07054



LOT: EXP:

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:62207-188-51	1 in 1 CARTON	04/18/2019	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62207-188-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	04/18/2019	

ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-183
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
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)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	

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:62207-183-51	1 in 1 CARTON	04/18/2019	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62207-183-34	1 in 1 BOX	06/30/2019	
2		5 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:62207-183-87	1 in 1 BOX	06/30/2019	
3		1 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:62207-183-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2019	
5	NDC:62207-183-97	40000 in 1 DRUM; Type 0: Not a Combination Product	03/25/2021	
6	NDC:62207-183-35	6 in 1 BOX	05/04/2024	
6		3000 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	04/18/2019	

Labeler - Granules India Limited (915000087)

Registrant - Granules India Limited (915000087)

