

REGULAR STRENGTH PAIN RELIEF- acetaminophen tablet
NuCare Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredients

Acetaminophen 325 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains
- temporarily reduces fever

Warnings

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 tablets 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

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.

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 symptom 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.

Overdose Warning:

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Keep out of reach of children.

Directions

- do not take more than directed
- adults and children 12 years and over: take 2 tablets every 4-6 hours, as needed; not more than 12 tablets in 24 hours
- children under 12 years: ask a doctor

Other Information

- **TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.**
- store at 20°C-25°C (68°F-77°F)
- for institutional use only

Inactive Ingredients

povidone, sodium starch glycolate, starch stearic acid. May also contain: crospovidone, methylparaben and propylparaben

Package Label

NuCare Pharmaceuticals, Inc.

NDC 66267-003-30
 Lot #: 000000 Exp. Date: 00-00

Acetaminophen 325mg #30 Tablets

Each tablet contains: Acetaminophen 325mg.
 Warnings: Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take more than 12 tablets 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. 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. 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.
 Round White Tablet Debossed: "GC 101" on one side

Acetaminophen 325mg #30 Tablets Exp Date: 00-00
 NDC 66267-0003-30 AWP: \$5.89
 Mfg NDC 57896-101-10
 Lot #: 000000 Rx # 23213444

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Product #: P0003030PED
 Rx # 23213444

WARNING: KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED TEMPERATURE 68-77°F.

REGULAR STRENGTH PAIN RELIEF

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66267-003(NDC:57896-101)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSPVIDONE (UNII: 68401960MK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	white (WHITE)	Score	2 pieces
Shape	ROUND (Round)	Size	10mm
Flavor		Imprint Code	M2A357344
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66267-003-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2016	
2	NDC:66267-003-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2016	
3	NDC:66267-003-25	25 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2016	
4	NDC:66267-003-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2016	
5	NDC:66267-003-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/16/2016	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)**Establishment**

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(66267-003)