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

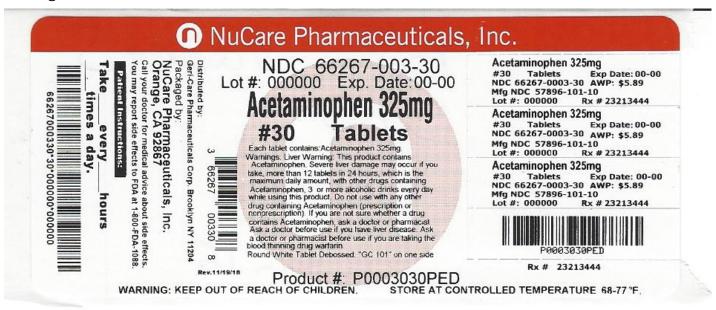
Other Information

- 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 probylparaben

Package Label



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

I	Active Ingredient/Active Moiety					
l	Ingredient Name	Basis of Strength	Strength			
l	ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg			

Inactive Ingredients			
Ingredient Name	Strength		
PO VIDO NE (UNII: FZ989 GH94E)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
STARCH, CORN (UNII: O8232NY3SJ)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
CROSPOVIDONE (UNII: 68401960 MK)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

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

P	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)	

Revised: 1/2020 NuCare Pharmaceuticals, Inc.