# 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.

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### **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

### Do not use

### Ask a doctor before use

if you have liver disease

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### Ask a doctor or pharmacist before use if you

are taking the blood thinning drug warfarin.

### Stop use and ask a doctor if

- 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
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

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.

- o 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

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:66267-999(NDC:57896-101) Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
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: 68401960MK)				
METHYLPARABEN (UNII: A218 C7H19 T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				

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

Packaging					
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1	NDC:66267-999-00	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	0 1/0 1/19 8 9	12/31/2018	

## Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment				
Name	Address	ID/FEI	Business Operations	
NuCare Pharmaceuticals,Inc.		010632300	relabel(66267-999)	

Revised: 3/2020 NuCare Pharmaceuticals,Inc.