ACETAMINOPHEN PAIN RELIEVER,FEVER REDUCER- 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.

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325 mg

Purposes

Pain reliever/fever reducer

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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 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 the user has

liver disease.

Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

Pain gets worse or lasts more than 10 days in adults and children

Pain gets worse or lasts more than 5 days in children under 12 years

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:

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. (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.

Uses

for the temporary relief of minor aches and pains due to:

- Headache
- Muscular aches
- Backache
- Minor pain of arthritis
- The common cold
- Toothache
- Premenstrual and menstrual cramps

Temporarily reduces fever.

Directions

Do not take more than directed

AGE	DOSE
Adults and Children 12 years and over	• Take 2 tablets every 4 to 6 hours while symptoms last • Do not take more than 12 tablets in 24 hours
Children 6 -	• Take 1 tablet every 4 to 6 hours while symptoms last • Do not take more than 5 tablets in 24 hours

11 years	• Do not take more than 5 tablets in 24 hours
Children under 6 years	Do not use adult Regular Strength products in children under 6 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.

Other information

- **Do not use if imprinted Safety Seal under cap is broken or missing**
- Store at room temperature

Inactive ingredients

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid.

Questions?

If you have any questions or comments, or to report an adverse event, please contact (800) 795-9775.

Principal Display Panel

ACETAMINOPHEN PAIN RELIEVER,FEVER REDUCER

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-4118(NDC:51645-703)

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)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (round)	**Score**	no score
Shape	ROUND (flat faced beveled edge)	**Size**	10mm
Flavor		**Imprint Code**	GPI;A325
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4118-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2017	
2	NDC:68071-4118-5	25 in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2017	
3	NDC:68071-4118-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2017	
4	NDC:68071-4118-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2017	
5	NDC:68071-4118-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/27/2006	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations

NuCare Pharmaceuticals,Inc.		010632300	repack(68071-4118)