

ACETAMINOPHEN- 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.

Acetaminophen 325 mg Tablets

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325 mg

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- backache
- minor pain of arthritis
- common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever.

Warnings

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- 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

- 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.

Directions

- **do not take more than directed (see overdose warning)**

| | |
|--|--|
| adults and children 12 years and over | <ul style="list-style-type: none"> • take 2 tablets every 4 to 6 hours while symptoms last • do not take more than 10 tablets in 24 hours, unless directed by a doctor • do not use for more than 10 days unless directed by a doctor |
| children 6 years to under 12 years | <ul style="list-style-type: none"> • take 1 tablet every 4 to 6 hours, while symptoms last • do not take more than 5 tablets in 24 hours • do not use for more than 5 days unless directed by a doctor |
| children under 6 years | ask a doctor |

Other information

- store at room temperature in a dry place

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**.

Distributed by: Plus Pharma, Commack, NY 11725

Manufactured in a GMP facility in the USA

 NuCare Pharmaceuticals, Inc.



GTIN 0036626785806
Serial# 0000000002
Exp. Date 00-00
LOT#: 000000

Take _____ every _____ hours

Caution: Do Not Exceed

Packaged By:
NuCare Pharmaceuticals, Inc. Orange, CA 92667
Call your doctor for medical advice about side effects.
You may report side effects to FDA at 1-800-FDA-1088.

Distributed by:
Plus Pharma, Commack, NY 11725

NDC: 66267-858-06
Acetaminophen 325mg
#6 Tablets

Round White Tablet Debossed: "GPI A325" on one side

Each tablet contains: Acetaminophen 325mg.....Pain reliever/fever reducer

Warnings: Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if, adult takes more than 4,000mg of Acetaminophen in 24 hours, 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 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 ingredients in this product.

Product #: P0858006ER



3 6 6 2 6 7 8 5 8 0 6

Acetaminophen 325mg
#6 Tablets Serial# 00000000002
Lot: 000000 NDC: 66267-0858-06
Exp.: 00-00 MFR NDC: 51645-703-01

Rev. 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN STORE AT CONTROLLED TEMPERATURE 59-86°F.

ACETAMINOPHEN

acetaminophen tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:66267-858(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:66267-858-06 | 6 in 1 BOTTLE; Type 0: Not a Combination Product | 12/16/2019 | |
| | | | | |
| 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(66267-858) |

Revised: 1/2021

NuCare Pharmaceuticals, Inc.