

ARTHRITIS PAIN RELIEVER- acetaminophen tablet, film coated, extended release

NuCare Pharmaceuticals, Inc.

DRUG FACTS

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen USP, 650 mg

PURPOSE

Pain reliever/fever reducer

USES (WHITE)

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

USES (RED)

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

WARNINGS

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

- more than 6 caplets 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

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 inactive ingredients in this product.

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 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:**

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 (WHITE)

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

Adults:

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

Under 18 years of age:

- ask a doctor

DIRECTIONS (RED)

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

Adults and children 12 years and over:

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

Children under 12 years:

- do not use

OTHER INFORMATION

- store at 20 - 25° C (68 - 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

INACTIVE INGREDIENTS (WHITE)

croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

INACTIVE INGREDIENTS (RED)

croscarmellose sodium, D&C red no. 30 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

QUESTIONS?

call **1-800-406-7984**

Contains No Aspirin

Keep the carton. It contains important information.

0115

Distributed by:

Ohm Laboratories Inc.

1385 Livingston Avenue

North Brunswick, NJ 08902

Principal Display Panel


NuCare Pharmaceuticals, Inc.

Take _____ every _____ hours
_____ times a day.

Caution Instructions:
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

NDC 68071-1552-5
Lot #: 000000 Exp. Date: 00-00

Acetaminophen 650mg
#50 E-R Caplets

See manufacturer's label
for full list of ingredients

Product #: R1521050

Acetaminophen 650mg
#50 E-R Caplets Exp Date: 00-00
NDC 68071-1552-05 AWP:
Mfg NDC 51660-333-50
Lot #: 000000 Rx # 22725790

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#50 E-R Caplets Exp Date: 00-00
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Lot #: 000000 Rx # 22725790

Rev. 01/10

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

ARTHRITIS PAIN RELIEVER

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-1552(NDC:51660-333)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

Color	white	Score	no score
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Shape	OVAL	Size	19mm
Flavor		Imprint Code	cor116
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
Marketing End Date			
1	NDC:68071-1552-5	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2017
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	04/30/2002	

Labeler -
NuCare Pharmaceuticals,Inc. (010632300)

Establishment			
Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-1552)