

**ARTHRITIS PAIN RELIEVER- acetaminophen tablet, film coated, extended release
Ohm Laboratories Inc.**

Arthritis Pain Relief

Drug Facts

Active ingredient (in each caplet)

Acetaminophen USP, 650 mg

Purpose

Pain reliever/fever reducer

Uses

- 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

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

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

| | |
|-----------------------|--|
| adults | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • ask a doctor |

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

croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone,

pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

Questions?

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

Distributed by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

PRINCIPAL DISPLAY PANEL - 650 mg CAPLET Bottle Carton

NDC 51660-333-50

† **Compare To the active ingredient of Tylenol® Arthritis Pain**

ohm®

Last up to 8 Hours

Use only as directed.

Arthritis Pain Relief

Acetaminophen

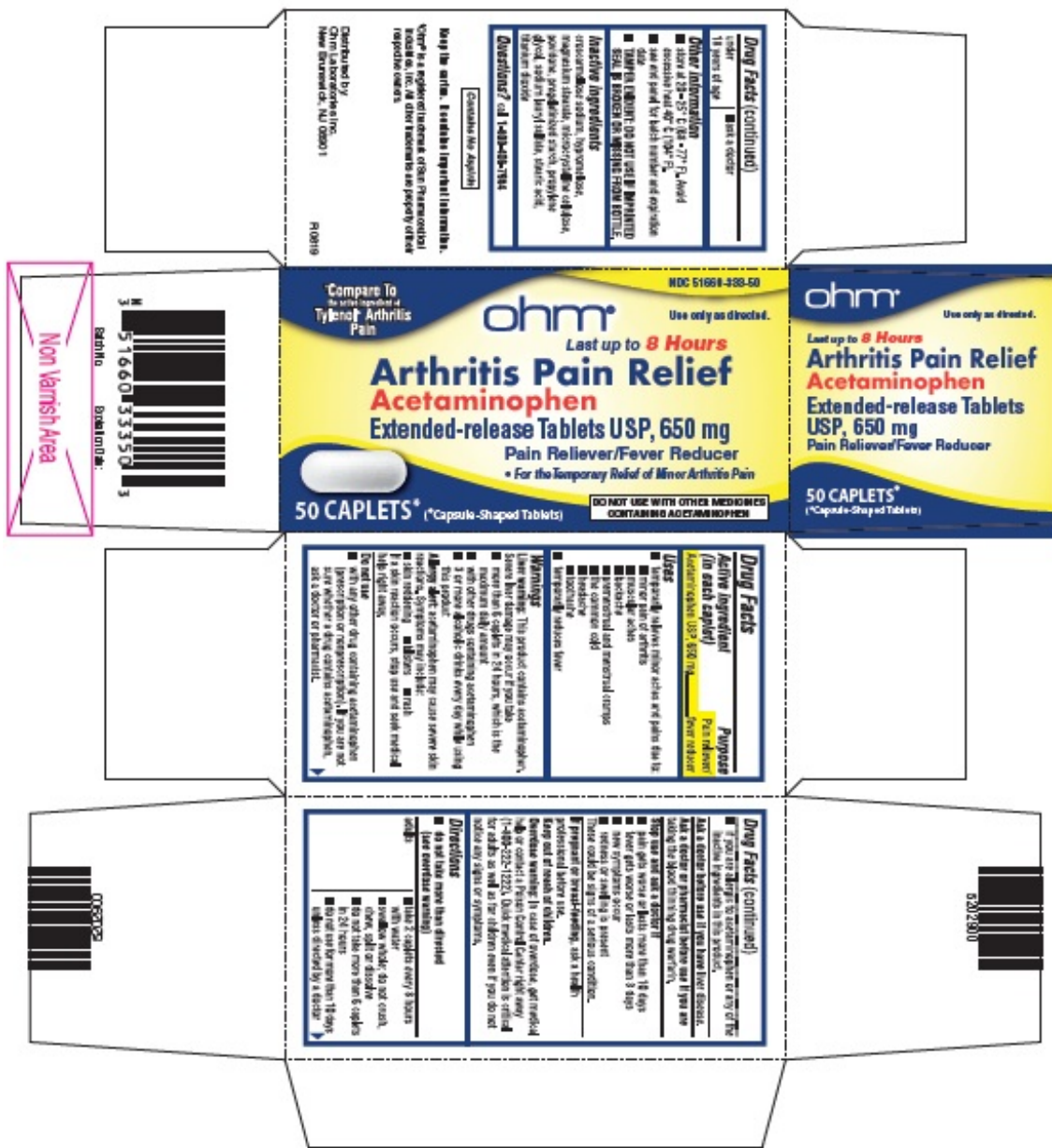
Extended-release Tablets USP, 650 mg

Pain Reliever/Fever Reducer

- *For the Temporary Relief of Minor Arthritis Pain*

**DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN**

50 CAPLETS* (*Capsule-Shaped Tablets)



Package/Label Principal Display Panel

NDC 51660-333-01

† Compare To the active ingredient of Tylenol® Arthritis Pain

ohm®

Last up to 8 Hours

Use only as directed.

**Arthritis Pain Relief
Acetaminophen
Extended-release Tablets USP, 650 mg
Pain Reliever/Fever Reducer**

- *For the Temporary Relief of Minor Arthritis Pain*

**DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN**

100 CAPLETS* (*Capsule-Shaped Tablets)



| ARTHRITIS PAIN RELIEVER | | | |
|---|----------------|--------------------|---------------|
| acetaminophen tablet, film coated, extended release | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | 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) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (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 |
| Shape | OVAL | Size | 19mm |
| Flavor | | Imprint Code | cor116 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:51660-333-01 | 1 in 1 CARTON | 04/30/2002 | |
| 1 | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:51660-333-50 | 1 in 1 CARTON | 04/30/2002 | |
| 2 | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076200 | 04/30/2002 | |

Labeler - Ohm Laboratories Inc. (184769029)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|------------------------|
| Ohm Laboratories Inc. | | 184769029 | MANUFACTURE(51660-333) |