**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release**
**Chain Drug Marketing Association Inc.**

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**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:
  - muscular aches
  - backache
  - headache
  - minor pain of arthritis
- 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

**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 and children 12 years and over | take 2 caplets every 8 hours with water<br>swallow whole - do not crush, chew, split or dissolve<br>do not take more than 6 caplets in 24 hours<br>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

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**

## PRINCIPAL DISPLAY PANEL

**QC QUALITY CHOICE®**

**NDC 63868-091-50**

**†Compare to the active ingredient in Tylenol® 8 Hour**

**Lasts up to 8 HOUR**

**Use only as directed.**

**See New Warnings Information**

**Acetaminophen**

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

**EXTENDED-RELEASE TABLETS, USP 650 mg**

**Pain Reliever/Fever Reducer**

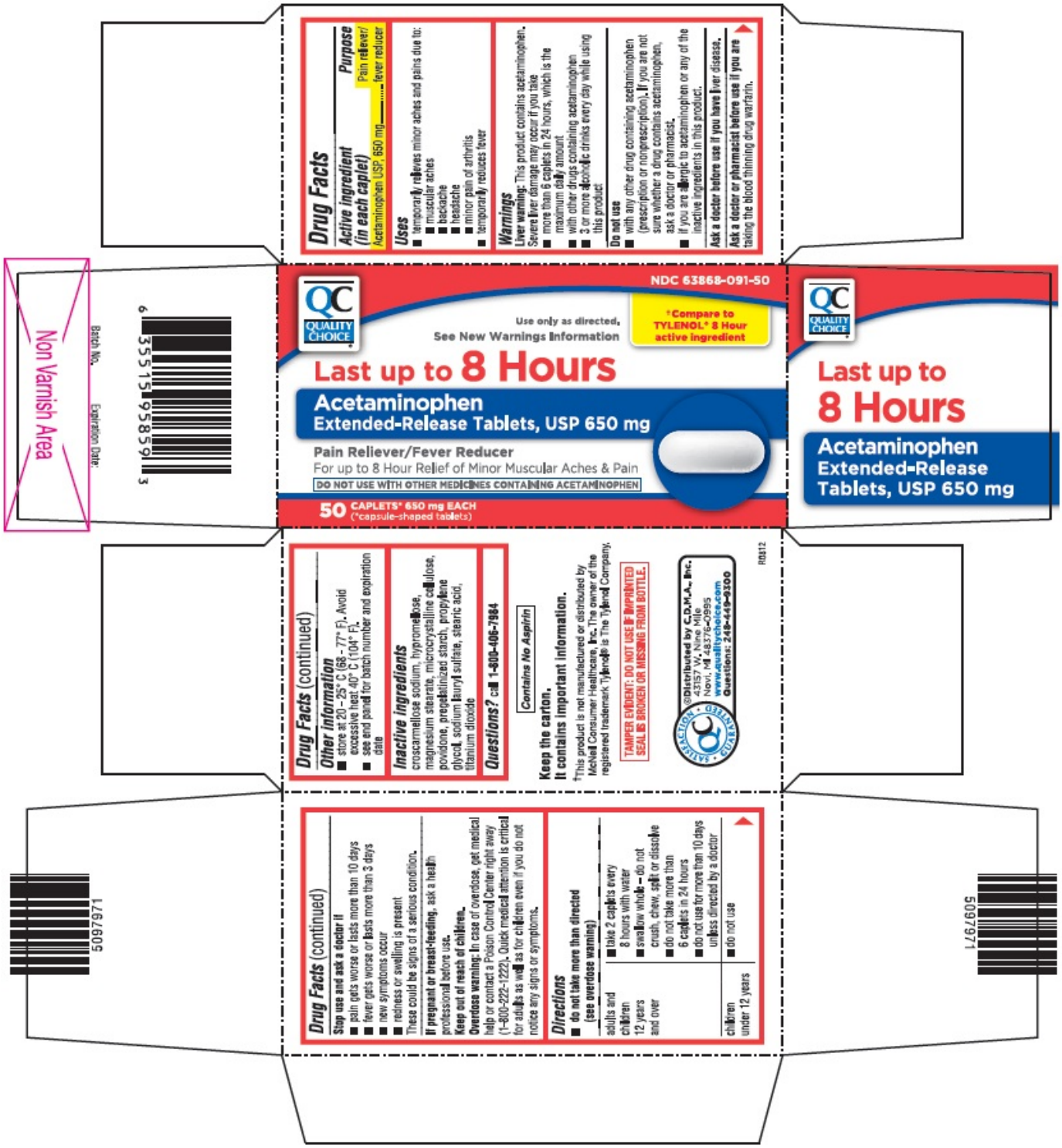
**For up to 8 Hour Relief of Minor Muscular Aches & Pain**

**50 CAPLETS* 650 mg EACH**

**(*capsule-shaped tablets)**

**©DISTRIBUTED BY QUALITY CHOICE**

**5097971/R0812**




## ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG LABEL | **Item Code (Source)** | NDC:63868-091 |
| **Route of Administration** | ORAL | **DEA Schedule** | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (ACETAMINOPHEN) | ACETAMINOPHEN | 650 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CROSCARMELLOSE SODIUM** | |
| **HYPROMELLOSES** | |
| **MAGNESIUM STEARATE** | |
| **CELLULOSE, MICROCRYSTALLINE** | |
| **POVIDONE** | |
| **STARCH, PREGELATINIZED CORN** | |
| **PROPYLENE GLYCOL** | |
| **SODIUM LAURYL SULFATE** | |
| **STEARIC ACID** | |
| **TITANIUM DIOXIDE** | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | OVAL (Capsule Shaped) | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | cor116 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63868-091-50 | 50 in 1 BOTTLE | | |
| **2** | NDC:63868-091-01 | 100 in 1 BOTTLE | | |

## Marketing Information

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

**Labeler -** Chain Drug Marketing Association Inc. (011920774)

## Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Ohm Laboratories Inc. | | 184769029 | manufacture(63868-091) |