ACETAMINOPHEN- acetaminophen tablet, extended release Walgreen Company

Acetaminophen

Drug Facts

Active ingredient (in each geltab)

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 geltabs 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 have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.
- 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
- the tablet got stuck in your throat

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 | take 2 geltabs every 8 hours. Swallow only one geltab at a time. take a sip of water before swallowing each geltab and wash each geltab down with water (up to a full 8 oz. glass). swallow whole; do not crush, chew, split or dissolve do not take more than 6 geltabs in 24 hours do not use for more than 10 days unless directed by a doctor |
|-----------------------|---|
| under 18 years of age | ask a doctor |

Other information

- store at 20 25° C (68 77° F). Avoid high humidity.
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

Inactive ingredients

croscarmellose sodium, gelatin, glycerin, hypromellose, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, starch (corn), titanium dioxide

Questions?

call 1-800-406-7984

DISTRIBUTED BY: WALGREEN CO., 200 WILMOT RD., DEERFIELD, IL 60015

PRINCIPAL DISPLAY PANEL - 650 mg Geltab Bottle Label

Walgreens

Compare to Tylenol® 8 HR Arthritis Pain active ingredient^{††}

EASY-OPEN

NDC 0363-0340-08

Arthritis Pain Reliever ACETAMINOPHEN EXTENDED-RELEASE TABLETS USP, 650 mg / PAIN RELIEVER / FEVER REDUCER

ARTHRITIS 8 HOUR

- For the temporary relief of minor arthritis pain
- Lasts up to 8 hours

ACTUAL SIZE

80 GELTABS* (*GELATIN-COATED TABLETS)

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Walgreens

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- premenstrual and menstrual cramps
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temporarily reduces fever

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69

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ITEM 952414 W00000-0000-0 ORG0818-F

Drug Facts (continued)

- more than 6 geltabs in 24 hours, which is the maximum daily amount
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- Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:
- skin reddening blisters rash

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- if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.
- 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.

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

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Drug Facts (continued)

Directions

do not take more than directed (see overdose warning)

adults

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- swallow whole; do not crush, chew, split or dissolve
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Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

Drug Facts (continued)

Other information

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- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

Inactive ingredients croscarmellose sodium, gelatin, glycerin, hypromellose, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, starch (corn), titanium dioxide

Questions? call 1-800-406-7984

^HAll trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Tylenol® 8 HR Arthritis Pain.

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ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-0340

Route of Administration

ORAL

| Active Ingredient/Active Moiety | | | |
|---|-------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D) | ACETAMINOPHEN | 650 mg | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357) | | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U) | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | |
| PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | |

| Product Characteristics | | | |
|-------------------------|-------------------------|--------------|----------|
| Color | white (White to Yellow) | Score | no score |
| Shape | ROUND | Size | 13mm |
| Flavor | | Imprint Code | 350 |
| Contains | | | |

| l | Packaging | | | |
|---|--------------------|---|----------------------|---------------------------|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 NDC:0363-0340-08 | 80 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2016 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA078569 | 05/01/2016 | |
| | | | |

Labeler - Walgreen Company (008965063)

Registrant - Ranbaxy Pharmaceuticals Inc. (947890044)

| Establishment | | | |
|---------------|---------|--------|---------------------|
| Name | Address | ID/FEI | Business Operations |

| Ohm Laboratories Inc. | 184769029 | MANUFACTURE(0363-0340) |
|-----------------------|-----------|------------------------|

Revised: 8/2018 Walgreen Company