**ACETAMINOPHEN- acetaminophen tablet**
**Richmond 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.*

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**ACETAMINOPHEN 325 mg**

**Active Ingredient**

**(in each tablet)**

Acetaminophen 325 mg

**Purpose**

Pain Reliever / Fever Reducer

**Uses**

temporarily reduces fever and relieves minor aches and pains caused by

- common cold
- headache
- toothache
- backache
- muscular aches
- minor pain of arthritis
- premenstrual and menstrual cramps

**Warnings**

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

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- child takes more than 5 tablets in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

**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.

**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**

- adult's pain gets worse or lasts more than 10 days
- child's pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear

**If pregnant or breast-feeding,** ask a health professional before use.

**Overdose warning**:Taking more than the recommended dose may cause liver damage. In case of

overdose contact Poisom Control Center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs of symptoms.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

**Directions**

| | |
|---|---|
| adults and children 12 years and over | 2 tablets every 4 to 6 hours while symptoms last, not more than 10 tablets in 24 hours. Do not use more than 10 days unless directed by doctor |
| children 6 to 11 years | 1 tablet every 4-6 hours while symptoms last, not more than 5 tablets in 24 hours. Do not use more than 5 days unless directed by doctor |
| children under 6 years | ask a doctor |

**Other Information**

store at 15-30 °C (59-86 °F)

**Inactive Ingredients**

polyvinylpyrrolidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

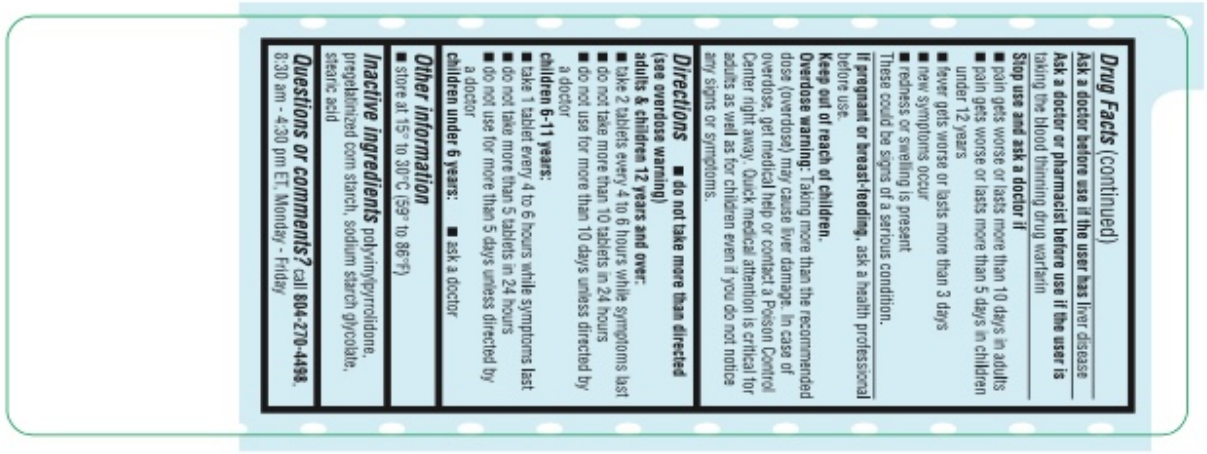
**Questions or Comments**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday**

**PRINCIPAL DISPLAY PANEL**

NDC- 54738-548-01... 100 APAP 325MG TABS


NDC- 54738-548-03... 1000 APAP 325MG TABS

NDC- 54738-548-50... 50 APAP 325MG TABS

# ACETAMINOPHEN

acetaminophen tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:54738-548 |
| **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 POTATO** (UNII: 5856J3G2A2) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | AP;012 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:54738-548-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2015 | |
| **2** | NDC:54738-548-03 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2015 | |
| **3** | NDC:54738-548-50 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2015 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part343 | 05/01/2015 | |

## Labeler - Richmond Pharmaceuticals, Inc. (043569607)

## Registrant - Advance Pharmaceutical Inc. (078301063)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Advance Pharmaceutical Inc. | | 078301063 | manufacture(54738-548) |

Revised: 10/2017 Richmond Pharmaceuticals, Inc.