**DUAL ACTION PAIN RELIEF- acetaminophen, ibuprofen tablet**
**TARGET CORPORATION**

---

**716R Target 11673-924 Acetaminophen 250 mg and Ibuprofen 125 mg Tablets**

***Drug Facts***

***Active ingredients (in each caplet)***
Acetaminophen 250 mg
Ibuprofen 125 mg (NSAID*)
*nonsteroidal anti-inflammatory drug

***Purposes***
Pain reliever
Pain reliever

***Uses***
temporarily relieves minor aches and pains due to:
- headache
- toothache
- backache
- menstrual cramps
- muscular aches
- minor pain of arthritis

***Warnings***
**Acetaminophen liver damage warning:**
This product contains acetaminophen. Severe liver damage may occur if you take:
• with other drugs containing acetaminophen
• more than 6 caplets in 24 hours, which is the maximum daily amount for this product
• 3 or more alcoholic drinks every day while using this product
**Acetaminophen allergy alert:** may cause severe skin reactions. Symptoms may include:
• skin reddening
• blisters
• rash
If skin reaction occurs, stop use and seek medical help right away.
**NSAID allergy alert:** ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
• hives
• facial swelling
• asthma (wheezing)
• shock
• skin reddening
• rash
• blisters
If an allergic reaction occurs, stop use and seek medical help right away.
**NSAID stomach bleeding warning:**

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
• are age 60 or older
• have had stomach ulcers or bleeding problems
• take a blood thinning (anticoagulant) or steroid drug
• take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
• have 3 or more alcoholic drinks every day while using this product
• take more or for a longer time than directed
**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**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 ever had an allergic reaction to acetaminophen or any other pain reliever
• right before or after heart surgery

**Ask a doctor before use if**
• you have liver disease
• stomach bleeding warning applies to you
• you have problems or serious side effects from taking pain relievers
• you have a history of stomach problems, such as heartburn
• you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
• you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**
• under a doctor’s care for any serious condition
• taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
• taking any other drug

**When using this product**
• take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**
you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better

you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body

- slurred speech
- leg swelling

pain gets worse or lasts more than 10 days
redness or swelling is present in the painful area
any new symptoms appear

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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**

| | |
|---|---|
| adults and children 12 years and over | ◦ **take 2 caplets every 8 hours** while symptoms persist |
| children under 12 years | ◦ ask a doctor |

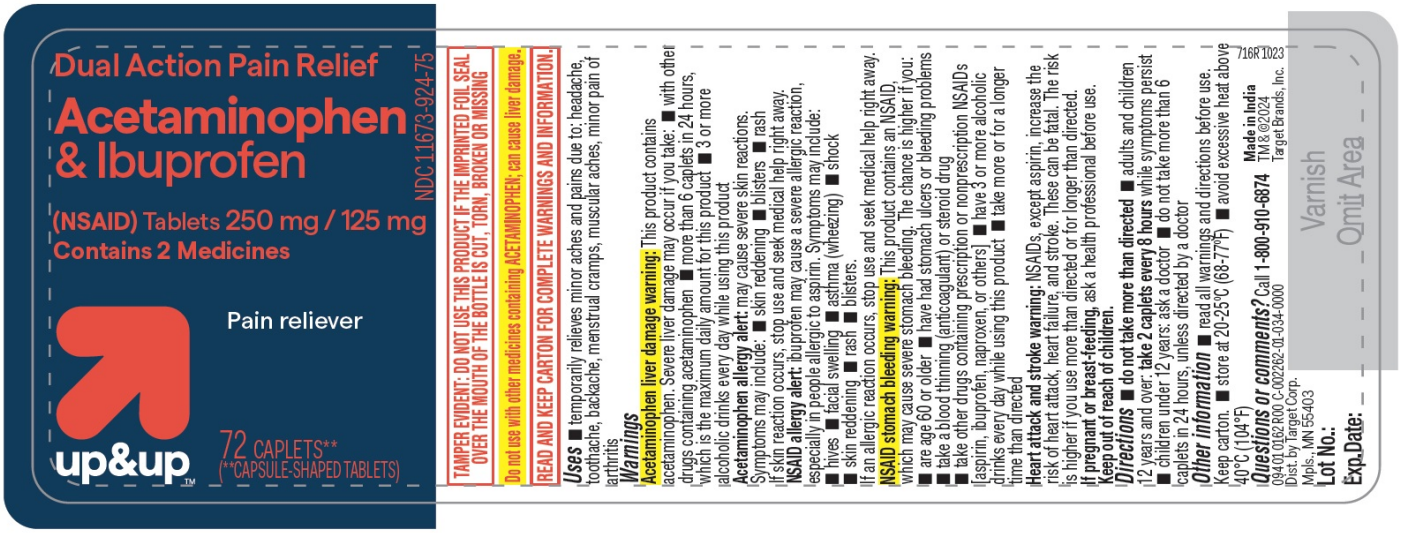
- do not take more than 6 caplets in 24 hours, unless directed by a doctor

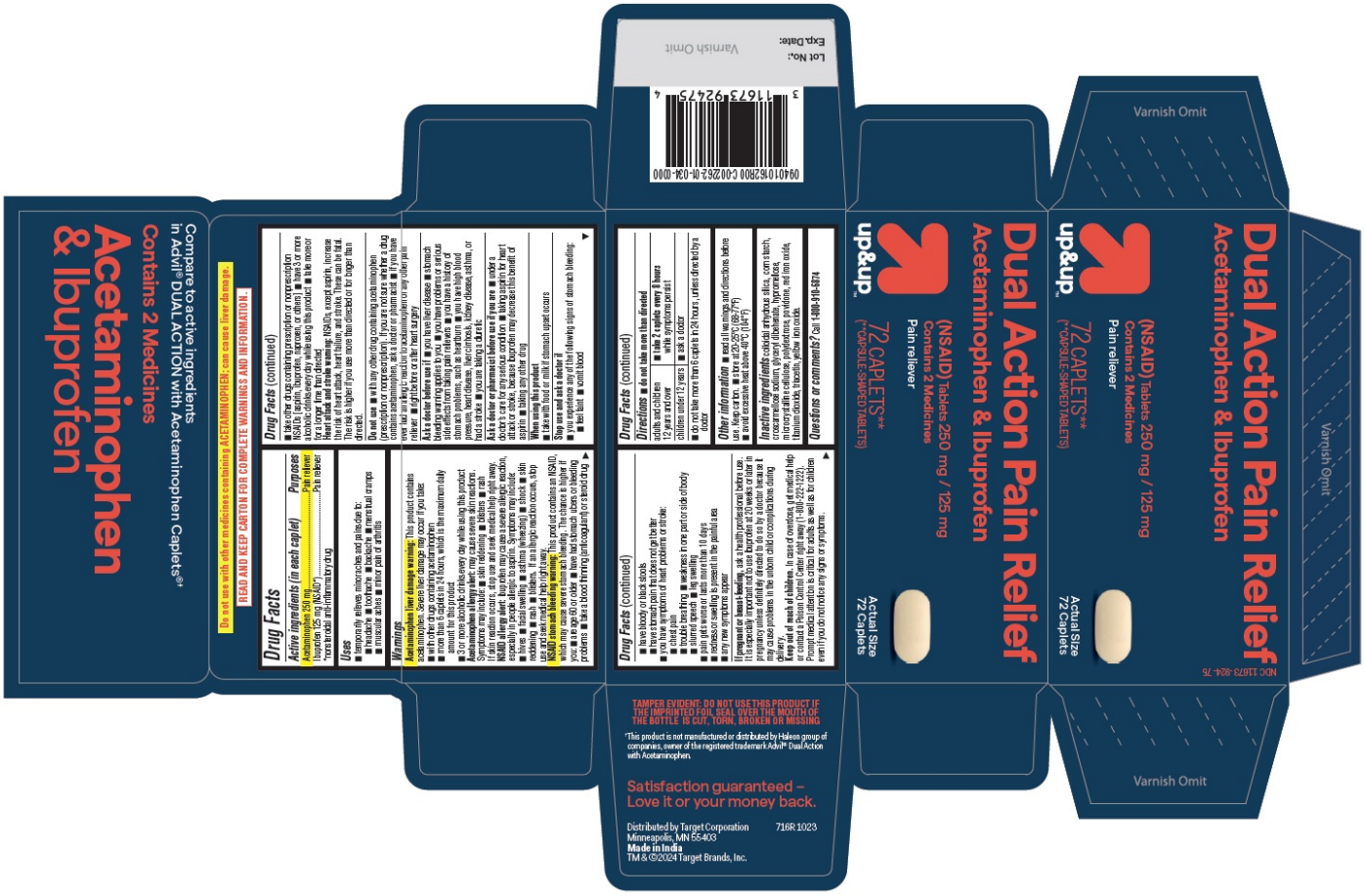
***Other information***

- read all warnings and directions before use. Keep carton.
- store at 20-25ºC (68-77ºF)
- avoid excessive heat above 40°C (104°F)

***Inactive ingredients*** colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, povidone, red iron oxide, titanium dioxide, triacetin, yellow iron oxide.

***Questions or comments?*** Call **1-800-910-6874**






# DUAL ACTION PAIN RELIEF

acetaminophen, ibuprofen tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:11673-924 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **IBUPROFEN** (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 125 mg |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 250 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **GLYCERYL DIBEHENATE** (UNII: R8WTH25YS2) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |

| | |
|---|---|
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | CAPSULE (Capsule shaped tablet) | **Size** | 15mm |
| **Flavor** | | **Imprint Code** | 80 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:11673-924-75 | 1 in 1 CARTON | 07/11/2023 | |
| **1** | | 72 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 | ANDA216994 | 07/11/2023 | |

## Labeler - TARGET CORPORATION (006961700)

## Registrant - TIME CAP LABORATORIES, INC. (037052099)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| MARKSANS PHARMA LIMITED | | 925822975 | manufacture(11673-924) |

Revised: 9/2024 TARGET CORPORATION