**IBUPROFEN- ibuprofen tablet, film coated**
**Central Texas Community Health Centers**

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**IBUPROFEN 200MG**

**Active ingredient (in each brown tablet)**

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever/fever reducer

**Uses**

- Temporarily relieves minor aches and pains due to:
- - headache
  - toothache
  - backache
  - menstrual cramps
  - the common cold
  - muscular aches
  - minor pain of arthritis
- Temporarily reduces fever

**Warnings**

**Allergy Alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- shock
- hives
- facial swelling
- asthma (wheezing)
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**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

**Do not use**
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**
- the stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

**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
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- fever gets worse or lasts more than 3 days
- any new symptoms occur

**If pregnant or breast-feeding,** ask a health professional before use. it is especially important not to use ibuprofen during the last 3 months of 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.

**Directions**
- **do not use more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not take more than 6 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

**Other information**

- store at controlled room temperature
- avoid excessive heat 40°C (104°F)

**Inactive ingredients**

carnauba wax, cellulose, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, PEG, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide.

**Questions or comments?**

Call 1-800-540-3765

**PRINCIPAL DISPLAY PANEL - 200 MG Tablet Bottle Box Label**

CommUnityCare Federally Qualified Health Centers

IBUPROFEN
200MG
TABS #100

Date:

Name:
Dr.

TAKE AS DIRECTED.

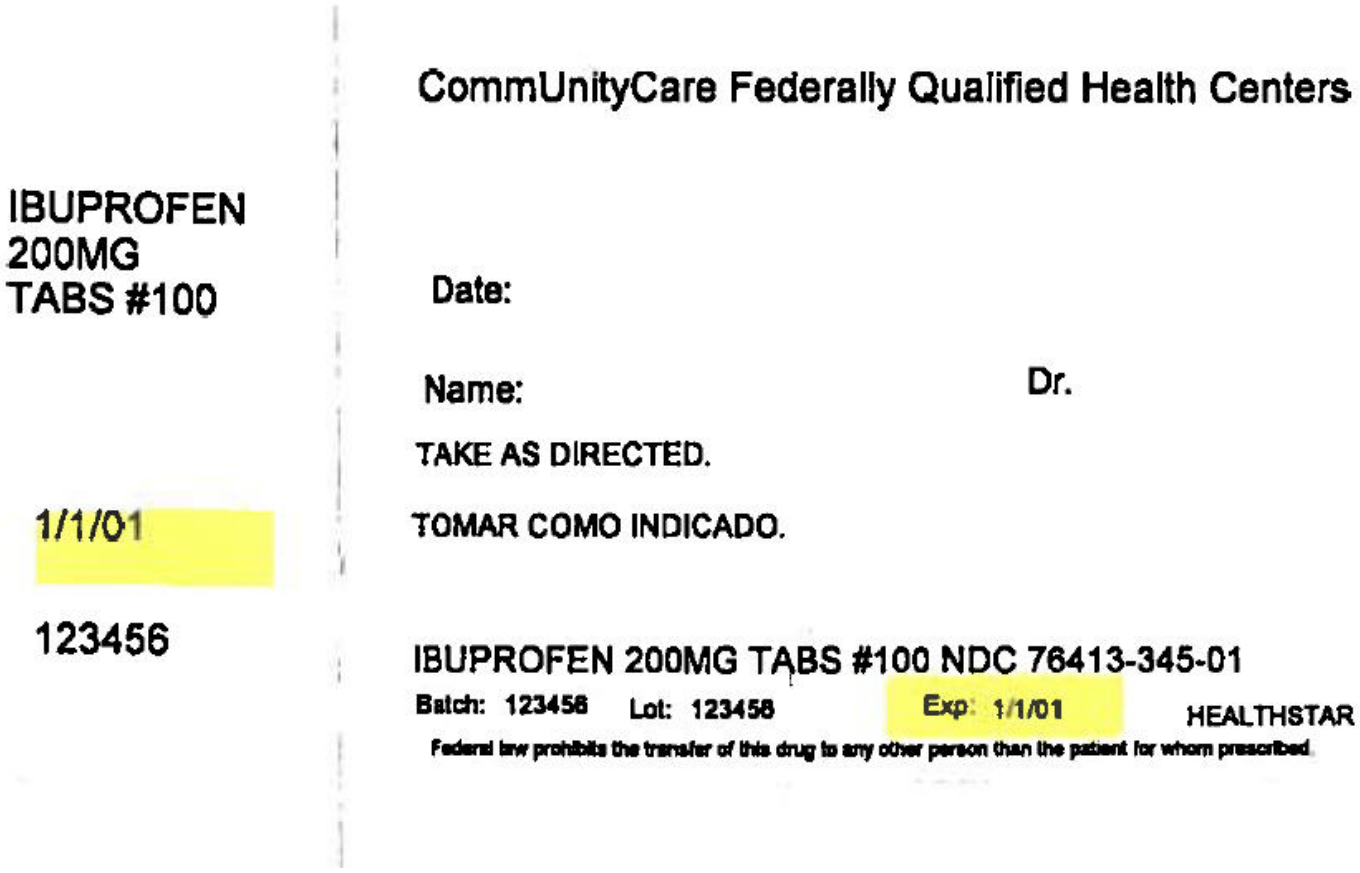
1/1/01

123456

IBUPROFEN 200MG TABS #100 NDC 76413-345-01

Batch:
123456
Lot:
123456
Exp:
1/1/01
HEALTHSTAR

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.




# IBUPROFEN

ibuprofen tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:76413-345(NDC:57896-941) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **IBUPROFEN** (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 200 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **LACTOSE, UNSPECIFIED FORM** (UNII: J2B2A4N98G) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |

| | |
|---|---|
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | brown | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | 44291 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:76413-345-01 | 1 in 1 BOX | 01/01/2004 | |
| **1** | | 100 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 | ANDA075010 | 01/01/2004 | |

## Labeler - Central Texas Community Health Centers (079674019)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Central Texas Community Health Centers | | 079674019 | REPACK(76413-345) , RELABEL(76413-345) |

Revised: 9/2017 Central Texas Community Health Centers