

ASPIRIN- aspirin tablet
Central Texas Community Health Centers

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.

Aspirin

Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)¹

¹ nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily relieves

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
- minor pain of arthritis

Warnings

Reye's syndrome

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

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 are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for

- gout
- diabetes
- arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- 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
- fever lasts more than 3 days
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. **It is especially important not to use aspirin 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

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 or 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
- children under 12 years: consult a doctor

Other information

- save carton for full directions and warnings
- store at room temperature

Inactive ingredients

carnauba wax², corn starch, hypromellose, powdered cellulose, triacetin

² may contain this ingredient

PRINCIPAL DISPLAY PANEL - 325 MG Tablet Bottle Carton

CommUnityCare Federally Qualified Health Centers

ASPIRIN
325 MG #
24
TABLETS

Date:

Name:
Dr.

TAKE AS DIRECTED.

123456

1/1/01

ASPIRIN 325 MG #24 TABS NDC 76413-303-24

Batch: 123456

Lot: 123456

Exp: 1/1/01

BAYER

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

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ASPIRIN
aspirin tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76413-303(NDC:0280-2000) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E) | Aspirin | 325 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|-----------------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| POWDERED CELLULOSE (UNII: SMD1X3XO9M) | |
| TRIACETIN (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | WHITE | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | BAYER |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76413-303-24 | 1 in 1 CARTON | 07/31/2014 | |
| 1 | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC MONOGRAPH NOT FINAL | part343 | 07/31/2014 | |

Labeler - Central Texas Community Health Centers (079674019)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--|----------------|---------------|--|
| Central Texas Community Health Centers | | 072827066 | REPACK(76413-303) , RELABEL(76413-303) |