

ASPIRIN- aspirin tablet, delayed release
HARRIS TEETER

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.

HTE - 1081B - 2019-1016 Correct DF, new NDC

Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- for the temporary relief of minor aches and pains due to:
 - headache
 - muscle pain
 - toothache
 - menstrual pain
 - colds
 - minor pain of arthritis
- or as recommended by your doctor

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 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:

- diabetes
- gout
- 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 for more than 10 days
- redness or swelling is present
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition

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 (1-800-222-1222).

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 hours while symptoms last; do not take more than 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

corn starch, croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

Harris Teeter

Enteric Coated Aspirin

†Compare to the Active Ingredient in Ecotrin® Regular Strength Aspirin

Regular Strength, 325 mg

PAIN RELIEVER (NSAID)

Safety Coated Aspirin

125 TABLETS

Actual Size

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING



F1081862HTE_R0

**DO NOT USE IF IMPRINTED SEAL
UNDER CAP IS BROKEN OR MISSING**



This product is not manufactured or distributed by Abbott. © Products Inc., distributor of Ecotrin® Regular Strength Aspirin.

Drug Facts

Active ingredient (in each tablet)
Aspirin 325 mg (NSAID)[†].....Pain reliever

Uses

- for the temporary relief of minor aches and pains due to:
 - colds
 - toothache
 - muscle pain
 - headache
 - menstrual pain
 - minor pain of arthritis
- or as recommended by your doctor

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
- shock
- asthma (wheezing)

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
- have had stomach burning (dyspepsia) or stomach drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

■ have 3 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 asthma

Drug Facts (continued)

- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

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:
 - vomit blood
 - have bloody or black stools

- have stomach pain that does not get better
 - pain gets worse or lasts for more than 10 days
 - redness or swelling is present
 - new symptoms occur
 - fever gets worse or lasts for more than 3 days
 - ringing in the ears or loss of hearing occurs
- These could be signs of a serious condition.

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 specifically 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).

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 hours while symptoms last. Do not take more than 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- store between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information and warnings

Drug Facts (continued)

Inactive ingredients ccm starch, croscarmellose sodium, DcC yellow #10 aluminum lake, FDcC yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, poly sorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-844-705-4384
PROUDLY DISTRIBUTED BY:
HARRIS TEETER, LLC
MATTHEWS, NC 28105
yourpharm
1-800-432-6111 or harristeeter.com
guarantee.

CN

†Compare to the Active Ingredient in Ecotrin® Regular Strength Aspirin



Enteric Coated Aspirin

Regular Strength 325 mg

PAIN RELIEVER (NSAID)

- Safety Coated Aspirin

125 TABLETS



Enteric Coated Aspirin

Regular Strength, 325 mg

PAIN RELIEVER (NSAID)

- Safety Coated Aspirin

125 TABLETS



†Compare to the Active Ingredient in Ecotrin® Regular Strength Aspirin

CN

CN

ASPIRIN

aspirin tablet, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:720 36-18 1 |
| 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 |
|---|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

Product Characteristics

| | | | |
|----------|--------|--------------|----------|
| Color | orange | Score | no score |
| Shape | ROUND | Size | 10 mm |
| Flavor | | Imprint Code | T |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72036-181-02 | 1 in 1 CARTON | 10/28/2014 | |
| 1 | | 125 in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 10/28/2014 | |

Labeler - HARRIS T EETER (047279351)

