

LEADER ASPIRIN- aspirin tablet, film coated
Cardinal Health 110, LLC. dba Leader

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.

Cardinal Health Aspirin Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID*)

*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 have ever had an allergic reaction to 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 gets worse or lasts more than 3 days
 - new symptoms occur
 - ringing in the ears or a 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 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

Inactive ingredients

corn starch, dibasic calcium phosphate dihydrate, hypromellose, talc, triacetin

Questions?

1-800-719-9260

Package/Label Principal Display Panel

Genuine | Adult

Aspirin Tablets, 325 mg | Pain Reliever Fever Reducer (NSAID)

Safe Pain Reliever Plus Lifesaving Benefits

Talk to Your Doctor or Other Healthcare Provider Before Using This Product for Your Heart.

100 COATED TABLETS

LEADER²

NDC 70000-0564-1

Genuine | Adult

Aspirin

Tablets, 325 mg | Pain Reliever
Fever Reducer (NSAID)

Safe Pain Relief
Plus Lifesaving Benefits

Talk to Your Doctor or Other Healthcare
Provider Before Using This Product for Your Heart.

100 COATED TABLETS

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

CIN 5646708 REV. 6/20



Drug Facts

Store at 20°-25°C (68°-77°F).

**Active ingredient
(in each tablet)**

Aspirin 325 mg (NSAID*).....Pain reliever/
fever reducer

Purposes

Uses temporarily relieves ■ menstrual pain
■ headache ■ toothache ■ pain and fever of
colds ■ minor pain of arthritis ■ muscle pain

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 ▶

PEEL BACK HERE ▶

GLUE AREA

Drug Facts (continued)

■ 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 ■ 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

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 gets worse or lasts more than
3 days ■ new symptoms occur ■ ringing in
the ears or a 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, ▼

GLUE AREA

Drug Facts (continued)

get medical help or contact a
Poison Control Center right away
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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 ▼

GLUE AREA

Drug Facts (continued)

Inactive ingredients

corn starch, dibasic calcium
phosphate dihydrate,
hypromellose, talc, triacetin

Questions?

1-800-719-9260

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Return to place of purchase if not satisfied.

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LEADER ASPIRIN

aspirin tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0564 |
| 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) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TRIACETIN (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | L37J |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70000-0564-1 | 1 in 1 CARTON | 08/19/2020 | |
| 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 |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 08/19/2020 | |

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader