

ASPIRIN 325 MG EC- aspirin tablet
Proficient Rx LP

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 325 MG EC TABLET

Drug Facts

Aspirin USP, 325 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Pain Reliever/Fever Reducer

temporarily relieves

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

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 (ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

Drug Facts continued on back of label

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 diabetes, gout or arthritis
- under a doctor's care for any serious condition
- taking any other drug

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
 - fever gets worse or lasts more than 3 days
 - redness or swelling is present in the painful area
 - any new symptoms appear
 - 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.

Directions

DRINK A FULL GLASS OF WATER WITH EACH DOSE

- **adults and children 12 years and over:** 1-2 tablets every 4 hours while symptoms last, not more than 12 tablets in 24 hours
- **children under 12 years:** ask a doctor

Other information

- store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

croscarmellose sodium, D&C yellow #10 (Al-lake), FD&C yellow #6 (Al-lake), HPMC, methacrylic acid copolymer, polyethylene glycol, propylene glycol, povidone, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide

Questions or comments?

Questions or comments ? call **516-341-0666**, 8:30 am - 4:30 pm ET, Monday - Friday


TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING


*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark Ecotrin®.

Distributed by: **Reliable 1 Laboratories LLC, Valley Stream, NY 11580**

Repackaged by: **Proficient Rx LP Thousand Oaks, CA 91320**

www.reliable1labs.com




Scan Here 

NDC 71205-318-60 Packaged By: Proficient Rx LP
Thousand Oaks, CA 91320

| | |
|--|----------------------------|
| Aspirin 325mg #60 EC Tablets Lot #:00000 NDC 71205-318-60 | SN# MASTER Exp:00/00/00 |
| Aspirin 325mg #60 EC Tablets Lot #:00000 NDC 71205-318-60 | SN# MASTER Exp:00/00/00 |
| Aspirin 325mg #60 EC Tablets Lot #:00000 NDC 71205-318-60 | SN# MASTER Exp:00/00/00 |

GTIN: 00371205318604
SN# MASTER
Exp 00/00/00
Lot #:00000



Aspirin 325mg
#60 EC Tablets

Each tablet contains: Aspirin USP, 325 mg (NSAID)* Pain Reliever/ Fever Reducer
*nonsteroidal anti-inflammatory drug

Round, orange colored, unscored tablet with imprint code "AP 110"

Product ID: QA031860
Dist. By: Reliable 1 Laboratories LLC, Valley Stream, NY 11580
Store at room temperature 15°-30°C (59°-86°F)

Keep medication out of the reach of children

NDC 71205-318-60

Enteric Coated

Aspirin USP 325 mg (NSAID)

PAIN RELIEVER

FEVER REDUCER

60 TABLETS

*Compare to Active Ingredients in Ecotrin®

ASPIRIN 325 MG EC

aspirin tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71205-318(NDC:69618-015) |
| 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 |
|---|----------|
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| METHACRYLIC ACID (UNII: 1CS02G8656) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | orange | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | AP;110 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71205-318-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/01/2019 | |
| 2 | NDC:71205-318-60 | 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/01/2019 | |
| 3 | NDC:71205-318-90 | 90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/01/2019 | |



ASPIRIN 325mg EC Tablet

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part343 | 11/01/2015 | |

Labeler - Proficient Rx LP (079196022)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|--|
| Proficient Rx LP | | 079196022 | REPACK(71205-318) , RELABEL(71205-318) |

Revised: 4/2022

Proficient Rx LP