

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
203697Orig1s000

LABELING

Drug Facts**Active ingredient (in each capsule) Purpose**

Aspirin (NSAID)* 325mg . . . Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

- for the temporary relief of minor aches and pains associated with:
 - a cold • headache • backache • toothache
 - premenstrual & menstrual cramps
 - minor pain of arthritis
- temporarily reduces fever

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.

Continue Reading 

Drug Facts (continued)

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

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

This product contains soy.

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 aspirin or any other pain reliever/fever reducer.

Ask a doctor before use if

- stomach bleeding warning applies to you

Drug Facts (continued)

- 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

Stop use and ask 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
- fever gets worse or lasts for more than 3 days

Reference ID: 3244830

Drug Facts (continued)

- redness or swelling is present in the painful area
- any new symptoms occur. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health care 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, consult a doctor 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 capsules every 4 hours or 3 capsules every 6 hours while symptoms persist
 - do not exceed 12 capsules in 24 hours
- children under 12 years: consult a doctor

Drug Facts (continued)**Other information**

- save carton for full directions and warnings
- store at 15 - 30°C (59 - 86°F)
- avoid excessive heat above 40°C (104°F)
- do not use if the blue band around the capsule is missing or broken

Inactive ingredients anhydrous citric acid, carrageenan, colloidal silicon dioxide, FD&C Blue #1, hypromellose, medium chain triglycerides, pharmaceutical ink, potassium chloride, soy lecithin, titanium dioxide

Questions or comments

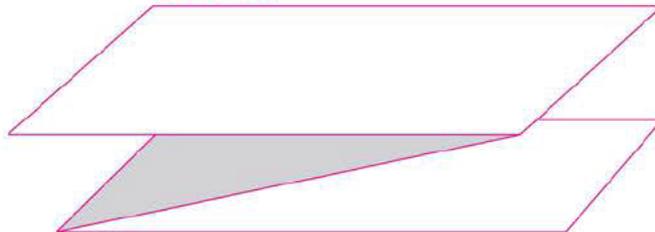
Call 1-800-123-4567 8:30 AM - 4:00 PM ET,
Monday - Friday



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8285 El Rio, Suite 130
Houston, TX 77054
Tel: 713-842-1249
Fax: 713-842-3052

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Fold Out Panel



NDC: 1234-5678-90

ASPIRIN
Aspirin Capsules, 325mg
Pain Reliever / Fever Reducer (NSAID)

30 Liquid Filled Capsules

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL WITH REPEATED TEXT "SEALED FOR YOUR PROTECTION" UNDER CAP IS MISSING OR BROKEN.

PEEL HERE FOR MORE DRUG FACTS 	
Drug Facts	Active ingredient (in each capsule) Aspirin (NSAID)* 325mg . . . Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug
Purpose	for the temporary relief of minor aches and pains associated with: • a cold • headache • backache • toothache • premenstrual & menstrual cramps • minor pain of arthritis • temporarily reduces fever
Uses	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.
Continue Reading 	Copy code Lot: XXXXXXXXX Exp: XX/XX/XXXX

Drug facts continued under label

Copy code

Lot: XXXXXXXXX
Exp: XX/XX/XXXX

No Print
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Drug Facts (continued)

- have had stomach ulcers or bleeding problems
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- 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 aspirin or any other pain reliever/fever reducer.

Ask a doctor before use if

- stomach bleeding warning applies to you
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- you are taking a diuretic
- you have asthma

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 - 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 for more than 3 days
- ringing in the ears or loss of hearing occurs
- redness or swelling is present in the painful area
- any new symptoms occur. These could be signs of a serious condition.



Drug Facts (continued)

If pregnant or breast-feeding, ask a health care 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.

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Questions or comments

Call 1-800-123-4567 8:30 AM - 4:00 PM ET, Monday - Friday



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ASPIRIN
Pain Reliever / Fever Reducer (NSAID)
30 Liquid Filled Capsules



TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL WITH REPEATED TEXT "SEALED FOR YOUR PROTECTION" UNDER CAP IS MISSING OR BROKEN.

30 Liquid Filled Capsules

ASPIRIN
Aspirin Capsules, 325mg
Pain Reliever / Fever Reducer (NSAID)

NDC# 1234-5678-90

RETAIN CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each capsule)

Aspirin (NSAID)* 325mg Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Purpose

Uses

- for the temporary relief of minor aches and pains associated with:
 - a cold
 - headache
 - backache
 - toothache
 - premenstrual & menstrual cramps
 - minor pain of arthritis
- temporarily reduces fever

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)
- This product contains soy.

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



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LOT & EXP

No Print
Glue Area

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Glue Area

Reference ID: 3244838

Drug Facts**Active ingredient (in each capsule)** **Purpose**

Aspirin (NSAID)* 325mg Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

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- have 1 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
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- 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

Reference ID: 3244830

↓ Continue Reading

**Drug Facts** (continued)**Stop use and ask doctor if**

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 - 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 for more than 3 days
- ringing in the ears or loss of hearing occurs
- redness or swelling is present in the painful area
- any new symptoms occur. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health care 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, consult a doctor get medical help or contact a Poison Control Center right away.

Directions

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Other information

- save carton for full directions and warnings
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Inactive ingredients anhydrous citric acid, carrageenan, colloidal silicon dioxide, FD&C Blue #1, hypromellose, medium chain triglycerides, pharmaceutical ink, potassium chloride, soy lecithin, titanium dioxide

Questions or comments

Call 1-800-123-4567 8:30 AM - 4:00 PM ET, Monday - Friday



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NDC#: 1234-5678-90

ASPIRIN

Aspirin Capsules, 325mg

Pain Reliever / Fever Reducer (NSAID)

120 Liquid Filled Capsules

Drug Facts**Active ingredient (in each capsule)** **Purpose**

Aspirin (NSAID)* 325mg Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

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 - a cold • headache • backache • toothache
 - premenstrual & menstrual cramps
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Allergy alert: Aspirin may cause a severe allergic reaction which may include:

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

 This product contains soy.

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 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 or arthritis

↓ Continue Reading



PEEL HERE FOR MORE DRUG FACTS

Drug facts continued under label

copy code

Lot: XXXXXXXX
Exp: XX/XX/XXXX

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL WITH REPEATED TEXT "SEALED FOR YOUR PROTECTION" UNDER CAP IS MISSING OR BROKEN.

FOR POSITION ONLY

No Print
Glue Area

120 Liquid Filled Capsules
Pain Reliever / Fever Reducer (NSAID)
ASPIRIN



TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL WITH REPEATED
TEXT "SEALED FOR YOUR PROTECTION" UNDER CAP IS MISSING OR BROKEN.

RETAIN CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

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NDC# 1234-5678-90

120 Liquid Filled Capsules

ASPIRIN
Aspirin Capsules, 325mg
Pain Reliever / Fever Reducer (NSAID)

Drug Facts (continued)

- have had stomach ulcers or bleeding problems
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Drug Facts (continued)

If pregnant or breast-feeding, ask a health care 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:
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- children under 12 years: consult a doctor

Other information

- save carton for full directions and warnings
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Inactive ingredients

anhydrous citric acid, carrageenan, colloidal silicon dioxide, FD&C Blue #1, hypromellose, medium chain triglycerides, pharmaceutical ink, potassium chloride, soy lecithin, titanium dioxide

Questions or comments

Call 1-800-123-4567 8:30 AM - 4:00 PM ET, Monday - Friday

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Lot & Exp



ASPIRIN

Aspirin Capsules, 325mg
Pain Reliever / Fever Reducer (NSAID)

Pharmaceuticals International, Hunt Valley, MD 21031

ASPIRIN

Aspirin Capsules, 325mg
(NSAID)

EXPIRES: 00/00/2013 LOT#: 012345

Pharmaceuticals International
Hunt Valley, MD 21031



ASPIRIN

Aspirin Capsules, 325mg
(NSAID)

EXPIRES: 00/00/2013 LOT#: 012345

Pharmaceuticals International
Hunt Valley, MD 21031



ASPIRIN

Aspirin Capsules, 325mg
(NSAID)

EXPIRES: 00/00/2013 LOT#: 012345

Pharmaceuticals International
Hunt Valley, MD 21031



TO OPEN:

Separate at the perforations and peel back paper from arrow.

Reference ID: A644830

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ASPIRIN
Aspirin Capsules, 325mg
(NSAID)

EXPIRES: 00/00/2013 LOT#: 012345

Pharmaceuticals International
Hunt Valley, MD 21031



ASPIRIN
Aspirin Capsules, 325mg
(NSAID)

EXPIRES: 00/00/2013 LOT#: 012345

Pharmaceuticals International
Hunt Valley, MD 21031



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EXPIRES: 00/00/2013 LOT#: 012345

Pharmaceuticals International
Hunt Valley, MD 21031



ASPIRIN
Aspirin Capsules, 325mg
(NSAID)

EXPIRES: 00/00/2013 LOT#: 012345

Pharmaceuticals International
Hunt Valley, MD 21031



FOR POSITION ONLY

TAMPER EVIDENT: DO NOT USE IF BLISTER IS OPEN OR TORN OR IF THE BAND AROUND THE CAPSULE IS MISSING OR BROKEN

Drug Facts

Active ingredient (in each capsule)

Aspirin (NSAID)* 325mg Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Purpose

Uses

- for the temporary relief of minor aches and pains associated with:
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Ask a doctor before use if

- stomach bleeding warning applies to you
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Drug Facts (continued)

- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
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Ask a doctor or pharmacist before use if you are

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Stop use and ask doctor if

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FOR POSITION ONLY

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Drug Facts (continued)

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Drug Facts (continued)

Questions or comments

Call 1-800-123-4567 8:30 AM - 4:00 PM ET, Monday - Friday



7 Liquid Filled Capsules

ASPIRIN
Aspirin Capsules, 325mg
Pain Reliever / Fever Reducer (NSAID)

NDC#: 1234-5678-90

Reference ID: 3244830

READ AND KEEP CARTON
FOR COMPLETE WARNINGS
AND INFORMATION



Visit us at www.aspirinxxx.com
Distributed by: Company XXX



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8258 Elm St, Suite 130
Houston, TX 77054
Tel: 713-842-1749
Fax: 713-842-3952

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Drug Facts (continued)

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Drug Facts (continued)
Questions or comments
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READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

ASPIRIN Aspirin Capsules, 325mg (NSAID)

28 Liquid Filled Capsules

ASPIRIN
Aspirin Capsules, 325mg
Pain Reliever / Fever Reducer (NSAID)

NDC#: 1234-5678-90

TAMPER EVIDENT: DO NOT USE IF BLISTER IS OPEN OR TORN OR IF THE BAND AROUND THE CAPSULE IS MISSING OR BROKEN

ASPIRIN
Aspirin Capsules, 325mg
Pain Reliever / Fever Reducer (NSAID)



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/s/

JOEL SCHIFFENBAUER
01/14/2013