**Drug Facts**

**Active Ingredient (In each capsule)**
- Aspirin (NSAID)* 325mg ... Pain reliever/fever reducer
- Nonsteroidal anti-inflammatory drug

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

**Warnings**
- Reye's syndrome: Children and teenagers who have or are recovering from chickenpox or flu-like symptoms should not use this product. When using this product, if fever gets worse or lasts more than 3 days, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.
- 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**
- 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)**

**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 thinner (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 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.

**Drug Facts (continued)**

**Inactive ingredients**
- anhydrous citric acid, cornstarch, colloidal silicon dioxide, FD&C Blue #1,
- hypromellose, medium chain triglycerides,
- pharmaceutical ink, potassium chloride, FD&C Yellow #6,
- titanium dioxide

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

**Diary of the Volunteer**

**Drug Facts (continued)**

**Other information**
- save carton for full directions and warnings
- store at 55 - 30°C (99 - 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, cornstarch, colloidal silicon dioxide, FD&C Blue #1,
- hypromellose, medium chain triglycerides,
- pharmaceutical ink, potassium chloride, FD&C Yellow #6,
- titanium dioxide

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

**Drug Facts (continued)**

**Active ingredient (In each capsule)**
- Aspirin (NSAID)* 325mg ... Pain reliever/fever reducer
- Nonsteroidal anti-inflammatory drug

**Uses**
- for the temporary relief of minor aches and pains associated with:
  - cold, headache, backache, toothache
  - premenstrual and menstrual cramps
  - minor pain of arthritis
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**Warnings**
- Reye's syndrome: Children and teenagers who have or are recovering from chickenpox or flu-like symptoms should not use this product. When using this product, if fever gets worse or lasts more than 3 days, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.
- 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**
- 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)**

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:
- hives
- facial swelling
- shock
- asthma (wheezing)

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- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinner (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 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.

**Drug Facts (continued)**

**Inactive ingredients**
- anhydrous citric acid, cornstarch, colloidal silicon dioxide, FD&C Blue #1,
- hypromellose, medium chain triglycerides,
- pharmaceutical ink, potassium chloride, FD&C Yellow #6,
- titanium dioxide

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

**Diary of the Volunteer**

**Drug Facts (continued)**

**Other information**
- save carton for full directions and warnings
- store at 55 - 30°C (99 - 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, cornstarch, colloidal silicon dioxide, FD&C Blue #1,
- hypromellose, medium chain triglycerides,
- pharmaceutical ink, potassium chloride, FD&C Yellow #6,
- titanium dioxide

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

**Drug Facts (continued)**

**Active ingredient (In each capsule)**
- Aspirin (NSAID)* 325mg ... Pain reliever/fever reducer
- Nonsteroidal anti-inflammatory drug

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

**Warnings**
- Reye's syndrome: Children and teenagers who have or are recovering from chickenpox or flu-like symptoms should not use this product. When using this product, if fever gets worse or lasts more than 3 days, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.
- 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**
- 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)

• have had stomach ulcers or bleeding problems
• take a blood thinning (anti-coagulant) or steriod drug
• take other drugs containing prescription or non-prescription 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

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
  • ringing in the ears or loss of hearing
  • redness or swelling is present in the painful area
• any new symptoms occur. These could be signs of a serious condition.

Active ingredient

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.

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

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 8:30AM - 4:00PM ET, Monday - Friday
Drug Facts

Active Ingredient (in each capsule) Purpose

Aspirin (ACS) 325mg Pain Reliever/ Fever Reducer (NSAID)

Uses

• for the temporary relief of minor aches and pains associated with:
  • cold, hay fever, arthritis
  • cold, hay fever, allergy
  • minor pain of arthritis
  • temporarily reduces fever

Warnings

Reye’s syndrome: Children and teenagers who have or are recovering from chickenpox or mononucleosis should not use this product. When using this product, parents or caregivers should be alert for symptoms of Reye’s syndrome (stomach pain, nausea, vomiting, headache, mental changes), which may be caused by aspirin. If these symptoms occur, contact a doctor immediately.

Do not use:

• if you have ever had an allergic reaction to aspirin or any other NSAID
• if you have had stomach ulcers or bleeding problems
• if you are allergic to any ingredient in this product

Ask a doctor before use if you:

• are taking any prescription or nonprescription medication that may affect stomach bleeding
• are age 60 or older
• have had stomach ulcers or bleeding problems
• have high blood pressure
• have asthma
• have diabetes
• have thyroid disease
• are taking any other drug

Other information

• do not use if you have had an allergic reaction to aspirin or any other NSAID
• do not exceed the recommended dosage

Inactive ingredients

• FD&C Blue No. 1, Hypromellose, FD&C Yellow No. 10,
  saccharin sodium, FD&C Red No. 40, and lecithin

Questions or comments

Call 1-800-123-4567 8:00 AM - 5:00 PM, Monday - Friday

Pliva Pharma Inc.
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Tel: 713-842-1249

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PRODUCTS}

120 Liquid Capsules

NSAID

120 Liquid Capsules

FRONT SIDE

The chance is higher if you:

• you are taking a diuretic
• you have high blood pressure, heart disease, liver or kidney disease
• you are taking aspirin, ibuprofen, naproxen, or other NSAID
• you have asthma

Ask the doctor before use if you:

• are allergic to aspirin or any other NSAID
• have a history of asthma, allergic reactions, hay fever, a history of aspirin allergy

Questions or comments

Call 1-800-123-4567 8:00 AM - 5:00 PM, Monday - Friday

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Fax: 713-432-3052
Tel: 713-842-1249

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**Drug Facts (continued)**

- **Active ingredient**: Aspirin (NSAID) 325mg
- **Purpose**: Pain reliever/fever reducer

**Uses**
- For the temporary relief of minor aches and pains associated with:
  - a cold
  - headache
  - backache
  - toothache
  - menstrual & 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 the flu-like symptoms 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

**Directions**
- Drink a full glass of water with each dose.
- Adults and children 12 years of age 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.

**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
Active ingredient (in each capsule)
Aspirin (NSAID)* 325 mg
Purpose
Pain reliever/fever reducer
Nonsteroidal anti-inflammatory drug

Uses
- For the temporary relief of minor aches and pains associated with:
  - Headache
  - Backache
  - Toothache
  - 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)

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 heart attack or stroke
- 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
- If you have a history of stomach problems, such as heartburn

Ask a doctor before use if:
- You have high blood pressure, heart disease, liver disease, or kidney disease
- You are taking a diuretic
- You have asthma

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
  - Worms in 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
  - Ringing in the ears or loss of hearing occurs
  - Redness or swelling is present in the pitiful 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 baby 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 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

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 blister is open or torn or if the band around the capsule is missing or broken

Inactive ingredients:
- Anhydrous citric acid, colloidal silicon dioxide, FD&C Blue No. 1, hypromellose, medium chain triglycerides, pharmaceutical grade talc, potassium chloride, red iron oxide, titanium dioxide

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

For complete warnings:
Read and keep this label
**Drug Facts**

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

**Aspirin (NSAID)** 325mg
- Pain relief/fever reducer

**Inactive ingredients**
- Amylum chloridum, cornstarch, colloidal silicon dioxide, FD&C Blue #1, hypromellose, medium chain triglycerides, pharmaceutical ink, potassium chloride, soy lecithin, titanium dioxide

**Warnings**
- Reye’s syndrome: Children and teenagers who have or are recovering from chicken pox or flu-slike symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occurs, consult a doctor because these symptoms could be an early sign of Reye’s syndrome, a rare but serious disease.
- Allergy alert: Aspirin may cause a severe allergic reaction which may include: fever, facial swelling, shock, or anaphylactic shock. This product contains soy.

**Soy**

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 drug (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
- If you have a history of stomach bleeding
- If you have ever had stomach bleeding
- If the pain is present in the painful area that does not get better
- If the pain gets worse or lasts more than 10 days
- If you have bloody or black stools
- If you are taking a prescription drug for diabetes, gout or arthritis
- If you have a history of high blood pressure, heart disease, liver cirrhosis, or kidney disease
- If you are taking a diuretic
- If you have asthma
- If you have had stomach problems, such as heartburn
- If you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer

**Other information**
- Save carton for full directions and warnings
- Avoid excessive heat above 40°C (104°F)
- Do not use if the blister is open or torn or if the band around the capsule is missing or broken

**Drug Facts (continued)**

- **Pain relief/fever reducer**
  - Ask a doctor or pharmacist before use if you are taking a prescription drug for diabetes, gout or arthritis
  - Ask a doctor or pharmacist before use if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer
  - Ask a doctor or pharmacist before use if you have a history of stomach bleeding

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

**References**
- Reference ID: 3244838
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
01/14/2013