

**CHRONIC PAIN/FEVER RELIEF- aspirin delayed release tablets, 81 mg tablet**  
**We Care Distributor Inc.**

*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.*

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**Chronic Pain/Fever Relief - Aspirin Delayed Release Tablets, 81 mg**

***Drug Facts***

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Active Ingredient (in each tablet)	Purpose
Aspirin 81 mg (NSAID*)	Pain reliever
*nonsteroidal anti-inflammatory drug	

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**Uses**

- for the temporary relief of minor aches and pains or as recommended by your doctor. **Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.**
- ask your doctor about other uses for 81 mg Aspirin

**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 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, or 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
  - any new symptoms occur
  - ringing in the ears or loss of hearing occurs

**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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- drink a full glass of water with each dose
- **adults and children 12 years and over:** take 4 to 8 tablets every 4 hours; not to exceed 48 tablets in 24 hours unless directed by a doctor
- **children under 12 years:** consult a doctor

**Other information**

- store at room temperature
- read all product information before using. Keep this box for important information

**Inactive ingredients**

Anhydrous Lactose, Carnuba Wax Colloidal Silicon Dioxide, Crosscarmellose Sodium, FD&C Yellow #10 al lake, FD&C Yellow #6 al Lake, Iron Oxide Ochre, Methacrylic acid copolymer, Micro crystalline cellulose, Polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc,

titanium dioxide, triethyl citrate

## Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or [www.wecaredistributor.com](http://www.wecaredistributor.com)

## PRINCIPAL DISPLAY PANEL

See New Warnings Information & Directions

Compare to the Active Ingredients in  
*Bayer Low Dose*


*Aspirin Delayed Release Tablets, 81 mg*

TO OPEN

PUSH IN TAB AND PULL OUT

25 Pouches of 2 Caplets Each

NDC: 70005-002-25



**CHRONIC PAIN/  
FEVER RELIEF**

COMPARE TO ACTIVE INGREDIENT IN

**Bayer Low Dose**®\*

TABLETS

Adult Low Dose Aspirin 81 mg  
Pain Reliever (NSAID)

*Safety Coated Aspirin Regimen*

\*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose Aspirin.

25 Pouches of 2 Coated Tablets

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

**Drug Facts**

**Active ingredient (in each tablet)**      **Purpose**  
Aspirin 81 mg (NSAID)\*      ...Pain reliever  
\*nonsteroidal anti-inflammatory drug

**Uses**  
■ For the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.  
■ Ask your doctor about other uses for 81 mg Aspirin.

**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 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**  
■ 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  
■ new symptoms occur ■ ringing in the ears or a loss of hearing occurs

**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 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor  
■ children under 12 years: consult a doctor

**Drug Facts (continued)**

**Other information** ■ store at room temperature

**Inactive ingredients** Anhydrous Lactose, Carruba Wax Colloidal Silicon Dioxide, Croscarmellose Sodium, FD&C Yellow #10 Lake, FD&C Yellow #6 Lake, Iron Oxide Ochre, Methacrylic acid copolymer, Micro crystalline cellulose, Polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate


**Questions or Comments**  
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Manufactured For / Distributed By:  
We Care Distributor Inc.  
Hermitage, TN 37076  
[www.wecaredistributor.com](http://www.wecaredistributor.com)

DO NOT USE IF POUCH IS  
BROKEN OR TORN

\*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose Aspirin.



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## CHRONIC PAIN/FEVER RELIEF

aspirin delayed release tablets, 81 mg tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-002
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	81 mg
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### Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

### Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	A
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-002-25	25 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-002-50	50 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-002-02	2 in 1 POUCH		
3		2 in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	02/09/2016	

**Labeler** - We Care Distributor Inc. (079832998)

### Establishment

Name	Address	ID/FEI	Business Operations
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Elysium Pharmaceutical Ltd.		915664486	manufacture(70005-002)
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Revised: 3/2016

We Care Distributor Inc.