# ASPIRIN LOW STRENGTH- aspirin tablet, delayed release CVS Pharmacy

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### CVS 44-645

## Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)\* \*nonsteroidal anti-inflammatory drug

#### Purpose

Pain reliever

#### 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.

# 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
- take a blood thinning (anticoagulant) or steroid drug
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

# Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

# 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 have asthma
- you are taking a diuretic

# 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:
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
  - feel faint
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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 at 20 weeks or later in 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

- do not take more than directed
- 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: do not use unless directed by a doctor

# Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

# Inactive ingredients

colloidal anhydrous silica, corn starch, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-426-9391

Principal Display Panel

VALUE SIZE 365 TABLETS

♥CVS Health<sub>®</sub>

Compare to the active ingredient in St. Joseph  $^{\mbox{\scriptsize B}}$  Low Dose Safety Coated 81 mg Aspirin  $^{\mbox{\scriptsize T}}$ 

# **Coated Tablets**

Low Strength **Aspirin** Pain reliever **(NSAID)** 

81

mg

Talk to your doctor or other healthcare provider before using this product for your heart.

Actual Size Safety Coated

**365** ENTERIC COATED TABLETS

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

<sup>†</sup>This product is not manufactured or distributed by Foundation Consumer Healthcare, LLC,

owner of the registered trademark St. Joseph<sup>®</sup> Low Dose Safety Coated 81 mg Aspirin.

**Distributed by: CVS Pharmacy, Inc.** One CVS Drive

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CVS 44-645

ASPIRIN LOW STREE aspirin tablet, delayed release					
Product Information					
Product Type	HUMAN OTC DRUG	Item Cod	e (Source)	NDC:5	9779-945
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredi	ent Name		<b>Basis of Stren</b>	gth	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIR	RIN - UNII:R16CO5Y76E)		ASPIRIN		81 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: 08232NY3SJ)	
FD&C RED NO. 40 (UNII: WZ B9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SHELLAC (UNII: 46N107B710)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

## **Product Characteristics**

Color	pink	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	L
Contains			

# Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779- 945-51	365 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/25/2014	
2	NDC:59779- 945-32	1 in 1 CARTON	07/25/2014	11/13/2025
2		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59779- 945-07	1 in 1 CARTON	07/25/2014	07/08/2018
3		36 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:59779- 945-17	1 in 1 CARTON	07/25/2014	03/04/2018
4		300 in 1 BOTTLE; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing

Application Number or Monograph Marketing Start Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M013	07/25/2014	

# Labeler - CVS Pharmacy (062312574)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(59779-945)
Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(59779-945)
Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(59779-945)
Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		868734088	manufacture(59779-945)
Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(59779-945)
Establishment			
	Address	ID/FEI	<b>Business Operations</b>
Name			-