# ADULT LOW STRENGTH ASPIRIN- as pirin tablet, coated WOONSOCKET PRESCRIPTION CENTER, INCORPORATED

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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#### CVS 44-414A

# Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

# Purpose

Pain reliever

#### Uses

temporarily relieves minor aches and pains

# **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
- shock
- facial swelling
- 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
- 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 any pain reliever or 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 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

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- and allergic reaction occurs
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present

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 prolems 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.

#### **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 while symptoms persist. Do not exceed 48 tablets in 24 hours or as directed by a doctor.
- children under 12 years: do not use unless directed by a doctor

#### Other information

- store at controlled room temperature 15°-30°F (59°-86°F)
- see end flap for expiration date and lot number

# **Inactive ingredients**

cellulose, colloidal silicon dioxidem croscarmellose sodium, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, shellac wax, simethicone, sodium alginate, sodium bicarbonate, starch, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

#### Questions or comments?

# **Principal Display Panel**

**CVS** 

pharmacy®

Compare to the actibe ingredient in St. Joseph® Adult Low Strength Aspirin\*\*

Adult Low Strength ASPIRIN PAIN RELIEVER (NSAID)

## NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

# 200 ADULT ENTERIC COATED TABLETS 81 mg each

# **EASY OPEN CAP**

\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark St. Joseph® Adult Low Strength Aspirin.

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CVS 44-414A

# ADULT LOW STRENGTH ASPIRIN

aspirin tablet, coated			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:59779-414
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active M	π·.		

Ingredient Name	Basis of Strength	Strength
ASPIRIN (ASPIRIN)	ASPIRIN	81 mg

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE			
CROSCARMELLOSE SODIUM			
FD&C RED NO. 40			
FD&C YELLOW NO. 6			
HYPROMELLOSES			
POLYDEXTROSE			
POLYETHYLENE GLYCOLS			
Polyvinyl Acetate Phthalate			
DIMETHICONE			
SO DIUM ALGINATE			
SO DIUM BICARBO NATE			
TALC			
TITANIUM DIO XIDE			
TRIACETIN			
TRIETHYL CITRATE			

Product Characteristics			
Color	PINK	Score	no score
Shape	ROUND	Size	8 m m
Flavor		Imprint Code	44;414
Contains			

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 N	DC:59779-414-06	1 in 1 BOTTLE, PLASTIC				
1		200 in 1 BOTTLE, GLASS				
2 N	DC:59779-414-07	1 in 1 CARTON				
2		36 in 1 BOTTLE, PLASTIC				
3 N	DC:59779-414-05	1 in 1 CARTON				
3		400 in 1 BOTTLE, PLASTIC				
4 N	DC:59779-414-17	1 in 1 CARTON				
4		300 in 1 BOTTLE, PLASTIC				
5 N	DC:59779-414-12	1 in 1 CARTON				
5		100 in 1 BOTTLE, PLASTIC				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part343	0 1/14/20 0 4		

# Labeler - woonsocket prescription center, incorporated (062312574)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(59779-414)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		038154464	PACK(59779-414)	

Revised: 11/2012

WOONSOCKET PRESCRIPTION CENTER, INCORPORATED