

**ADULT ASPIRIN REGIMEN LOW DOSE- aspirin tablet, coated  
REMEDYREPACK 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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**Leader 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:

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

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed
- have had stomach ulcers or bleeding problems
- 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 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:
  - vomit blood
  - have bloody or black stools
  - feel faint
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 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 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.

**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: 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)
- see end flap for expiration date and lot number

**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**

DRUG: Adult Aspirin RegimenLow Dose Low Dose

GENERIC: Aspirin

DOSAGE: TABLET, COATED

ADMINISTRATION: ORAL

NDC: 70518-3025-0

NDC: 70518-3025-1

NDC: 70518-3025-2

NDC: 70518-3025-3

COLOR: pink

SHAPE: ROUND

SCORE: No score

SIZE: 6 mm

IMPRINT: L

PACKAGING: 90 in 1 BOTTLE, PLASTIC

PACKAGING: 30 in 1 BOX

PACKAGING: 1 in 1 POUCH

PACKAGING: 30 in 1 BOTTLE PLASTIC

ACTIVE INGREDIENT(S):

- ASPIRIN 81mg in 1

INACTIVE INGREDIENT(S):

- SILICON DIOXIDE
- STARCH, CORN
- FD&C RED NO. 40
- FD&C YELLOW NO. 6
- HYPROMELLOSE, UNSPECIFIED
- METHACRYLIC ACID
- MICROCRYSTALLINE CELLULOSE
- POLYDEXTROSE
- POLYETHYLENE GLYCOL, UNSPECIFIED
- SODIUM BICARBONATE
- SODIUM LAURYL SULFATE
- TALC
- TITANIUM DIOXIDE
- TRIACETIN
- TRIETHYL CITRATE
- SHELLAC

## ADULT ASPIRIN REGIMEN LOW DOSE

aspirin tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70518-3025(NDC:70000-0218)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY35J)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>METHACRYLIC ACID</b> (UNII: 1CS02G8656)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>SHELLAC</b> (UNII: 46N107B71O)	

**Product Characteristics**

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	L
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-3025-0	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/18/2021	
2	NDC:70518-3025-1	30 in 1 BOX	03/29/2021	
2	NDC:70518-3025-2	1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70518-3025-3	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/30/2021	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/18/2021	

**Labeler** - REMEDYREPACK INC. (829572556)

Revised: 8/2021

REMEDYREPACK INC.