LOW DOSE ASPIRIN- aspirin tablet, coated McKesson Corporation dba SKY Packaging

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.

TCL 481R TABLETS

Active Ingredient (in each tablet)

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

Purpose

Pain Reliever

Uses

temporary relief of minor aches and pains

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 enteric-coated 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 aspirinor 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
- you have not been drinking fluids
- you have lost a lot of fluid due to vomiting or diarrhea

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, arthritis
- taking any other drug
- under a doctor's care for any serious condition

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 loss of hearing occurs

These could be signs of 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 specifically 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 accidental overdose, get medical help or contact a Poison Control Center(1-800-222-1222) immediately.

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

Inactive Ingredients

anhydrous lactose, carnauba wax, colodial sillicon dioxide, croscarmellose sodium, D&C yellow # 10 aluminum lake, iron oxide ochre, methacrylic acid and ethylacrylate copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

HOW SUPPLIED

Product: 63739-212

NDC: 63739-212-10 10 TABLET, COATED in a BLISTER PACK / 10 in a BOX

NDC: 63739-212-01 25 TABLET, COATED in a BLISTER PACK / 30 in a BOX

LOW DOSE ASPIRIN (ASPIRIN) TABLET, COATED

ASPIRIN

DELAYED-RELEASE
ENTERIC COATED
TABLETS 81 mg
UD 100 Tablets (10x10)

LOT: [Text LOT]

EXP: [Text EXP]



A SPIRIN

DELAYED-RELEASE
ENTERIC COATED
TABLETS 81 mg
UD 100 Tablets (10x10)



 temporarily relieves minor aches and pairs
 Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.

ask your doctor about uses for enteric-coated 81 mg.
 Aspirin

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

Do not use if you are allergic to aspirin or any other pain reliever/fever reducer

For Directions and Warnings: See accompanying Patient Insert Consult a physician before the use of this product. In case of overdose, get medical help or contact a

Other information: * store at 25°C (77°F) excursions permitted between 15"-30°C (59"-86°F)

· use by expiration date on package

Poison Control Center right away.

Mfg. By: Time-Cap Labs 7 Michael Ave. Farmingdale, NY 11735

LS-401 7641

Aspirin DR Enteric Coated Tablet 81 mg

Lot: 1111111 Exp: Nov 2011



Dist By: McKesson, Memphis, TN 38141

LOW DOSE ASPIRIN (ASPIRIN) TABLET, COATED

NDC 63739-212-01

ASPIRIN DELAYED-RELEASE ENTERIC COATED TABLETS 81 mg

UD 750 Tablets (25x30)

Dist.By: McKesson Corporation 4971 Southidge Blvd, Suite 101 Memphis, TN 38141





NDC 63739-212-01

ASPIRIN DELAYED-RELEASE ENTERIC COATED TABLETS 81 mg

UD 750 Tablets (25x30)

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Do not use if you are allergic to aspirin or any other pain reliever/flever reducer.

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FOR INSTITUTIONAL USE CITE.Y
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L3-40 17643

Aspirin DR Enteric Coated Tablet 81mg



N (01)003 63739 212 01 5 Dist By: McKesson, Memphis, TN 38141

LOW DOSE ASPIRIN

Drug Fects

Active ingredient (in each tablet)

Purpose Pain Reliever

Aspirin 81 mg (NSAID"). onsteroidal orb-inflammatory drug

Uses a temporarily relieves minor aches and pains

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Ask a doctor before use if a stomach bleeding warning applies to you a you have a history of stomach problems, such as heartburn a you have high blood pressure, heart disease, liver cirrhosis, or kidney disease a you are taking a diuretic a you have asthma a you have not been drinking fluids a you have lost a lot of fluid due to vomiting or diarrhea Ask a doctor or pharmacist

before use if you are taking a prescription drug for diabetes, gout, or arthritis a taking any other drug a under a doctor's care for any serious condition 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 a have stomach pain that does not get better a pain gets worse or lasts more than 10 days a redness or swelling is present a new symptoms occur a ringing in the ears or loss of hearing occurs

These could be signs of 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 specifically 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) immediately.

Directions a drink a full glass of water with each dose a adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 49 tablets in 24 hours unless directed by a doctor a children under 12 years: consult a doctor

Other (information: a store at 25°C [77°F) excursions permitted between 15°-30°C (59°-86°F) a use by expiration date on package a save carton for full directions and warnings a do not use if blister

card is damaged or appears to have been tampered Inactive Ingredients anhydrous lectors, carnauba wax, colloidal silicon dioxide, croscannellose sodium, D&C yellow #10 aluminum lake, iron oxide othre, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80. simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc. titanium dioxide, triethyl citrate

Mig.By: Time-Cap Labs, Inc. 7 Michael Avenue Famingdale, NY 11735 Dist. By: McKasson Carporation, Memphie, TN 38141 †This product is not amounted and distributed by Bayer Healthcare L This product is not manufactured or as movies by says.

Although the registered trademark Bayer'S Law Dase. 481 R 9218



Low-Dose ASPIRIN DELAYED-RELEASE ENTERIC - COATED

NDC 63739-212-02



Tablets, 81 mg (NSAID*) UD 300 Tablets (30x10)

LOT 1234567890

EXP YYYY-MM-DD

(01)10363739212029

91894

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LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63739-212(NDC:49483-481)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	AS PIRIN	81 ma	

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y10)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	HEART
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63739- 212-10	10 in 1 BOX	02/01/2020	07/31/2021
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63739- 212-01	30 in 1 BOX	02/01/2020	06/30/2021
2		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63739- 212-02	30 in 1 BOX	03/18/2021	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Category	Citation	Date	Date
OTC monograph not final	part343	06/19/2015	

Labeler - McKesson Corporation dba SKY Packaging (140529962)

Revised: 10/2021 McKesson Corporation dba SKY Packaging