

**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.*

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**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 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
- 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 silicon 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**

NDC 63739-212-10  
**ASPIRIN**  
**DELAYED-RELEASE**  
ENTERIC COATED  
**TABLETS 81 mg**  
UD 100 Tablets (10x10)

LOT: [Text LOT]

EXP: [Text EXP]



NDC 63739-212-10  
**ASPIRIN**  
**DELAYED-RELEASE**  
ENTERIC COATED  
**TABLETS 81 mg**  
UD 100 Tablets (10x10)



(01)10363739212104

**Active Ingredient (in each tablet)**      **Purpose**  
Aspirin 81 mg (NSAID\*).....Pain reliever

\*nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves 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 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 Poison Control Center right away.

**Other information:** • store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)  
• use by expiration date on package

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

LS-4017641

**Aspirin DR Enteric  
Coated Tablet 81 mg**

Lot: 1111111      Exp: Nov 2011



N (01)003 63739 212 10 7

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 Southridge Blvd, Suite 101  
Memphis, TN 38141



NDC 63739-212-01

**ASPIRIN  
DELAYED-RELEASE**

ENTERIC COATED  
**TABLETS 81 mg**  
UD 750 Tablets (25x30)

**Drug Facts**

Active ingredient(s) in each tablet	Purpose
Aspirin 81 mg (NSAID)*	Pain reliever

\*Nonsteroidal anti-inflammatory drug

**Uses** - Temporarily relieves 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 - 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 - 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 disease, 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, or 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 - have bloody or black stools - vomit blood - 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 These could be signs of a serious condition.

**If pregnant or breastfeeding,** ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless explicitly 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** - drink a full glass of water with each dose - adults and children 12 years and over: take 1 to 2 tablets every 4 hours not to exceed 6 tablets in 24 hours unless directed by a doctor - children under 12 years: consult a doctor

**Other information** - store at 20°C (67°F) excursions permitted between 15°-30°C (59°-86°F) - use by aspirin or aspirin package

**Active ingredients** - aspirin, salicylic acid, croscarmellose sodium, croscarmellose sodium, DIB, yellow #10, duminum lake, iron oxide black, polyethylene glycol 400, hydroxyethylcellulose, croscarmellose sodium, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

**Mfg. By:** Time-Caps Labs, 7 Mohawk Ave., Farmingdale, NY 11735

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

FOR INSTITUTIONAL USE ONLY  
See package for expiration date and lot number

L5-40 17643

**Aspirin DR Enteric Coated  
Tablet 81mg**

Lot: 1111111 Exp: Nov 2011



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

**LOW DOSE ASPIRIN**

**Drug Facts**

**Active ingredient (in each tablet)** **Purpose**

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

**Use** ■ temporarily relieves 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 ■ 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 ■ 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 ■ 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, or 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 overdose, get medical help or contact a Poison Control Center (1-800-322-1222) 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

**Other information** ■ store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F) ■ use by expiration date on package ■ save carton for full directions and warnings ■ do not use if blister card is damaged or appears to have been tampered

**Inactive ingredients** anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

Mfg. By: Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, NY 11735  
Dist. By: McKesson Corporation, Memphis, TN 38141  
†This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Bayer® Low Dose. 481R 021R

**SKY** Low-Dose NDC 63739-212-02  
**ASPIRIN DELAYED-RELEASE**  
**ENTERIC-COATED**

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

LOT 1234567890  
 EXP YYYY-MM-DD

  
 (01)10363739212029

91094 R-03 00000

# LOW DOSE ASPIRIN

aspirin tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63739-212(NDC:49483-481)
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Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

### Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
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
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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