# HEALTH SENSE ASPIRIN 81- 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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#### health sense 981

#### 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
- ask your doctor about other uses for 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 your are allergic to aspirin or any other pain reliever/fever reducer.

#### Ask a doctor before use if

- the stomach bleeding warning applies to you
- you are taking a diuretic
- you have a history of stomach problems, such as heartburn

• you have: -high blood pressure -heart disease -liver cirrhosis -kidney disease -asthma

#### Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- taking a prescription drug for diabetes, gout or arthritis

#### Stop use and ask a doctor if

- 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
- an allergic reaction occurs. Seek medical help right away
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

#### 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 right away.

#### Directions

- drink a full glass of water with each dose
- swallow whole, do not chew or crush
- do not exceed recommended dose
- adults and children 12 years and older: take 4-8 tablets every 4 hours, as needed, not more than 48 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

#### Other information

• store at room temperature 150C - 300C (590F - 860F)

#### **Inactive ingredients**

cellulose, D&C yellow #10 lake, FD&C yellow #6 lake, hypromellose, iron oxide, methacrylic acid, PEG, polydextrose, propylene glycol, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, starch, talc, titanium dioxide, triacetin, triethyl citrate, wax. May also contain: acetylated monoglycerides, croscarmellose sodium, hypromellose phthalate, lactose, mineral oil, polysorbate 80, stearic acid.

DRUG: HEALTH SENSE ASPIRIN 81

**GENERIC:** Aspirin

#### DOSAGE: TABLET, COATED

ADMINSTRATION: ORAL

NDC: 70518-0923-0

COLOR: yellow

SHAPE: ROUND

SCORE: No score

SIZE: 6 mm

IMPRINT: L

PACKAGING: 30 in 1 BLISTER PACK

ACTIVE INGREDIENT(S):

• ASPIRIN 81mg in 1

INACTIVE INGREDIENT(S):

- TRIETHYL CITRATE
- TITANIUM DIOXIDE
- TALC
- SODIUM LAURYL SULFATE
- SODIUM BICARBONATE
- DIMETHICONE
- SILICON DIOXIDE
- SHELLAC
- TRIACETIN
- PROPYLENE GLYCOL
- POLYDEXTROSE
- CELLULOSE, MICROCRYSTALLINE
- METHACRYLIC ACID
- HYPROMELLOSES
- FD&C YELLOW NO. 6
- D&C YELLOW NO. 10
- STARCH, CORN
- POLYETHYLENE GLYCOL, UNSPECIFIED
- FERROSOFERRIC OXIDE

# Aspirin

# 81 mg Tablet, EC

 ID #:
 Ex

 NDC #:
 70518-0923-00
 Sh

 LOT #:
 Re

 MFG:
 HealthSense, Mendota Heights, MN 55120

 NOT FOR RETAIL SALE

### **Directions For Use: See Package Insert**

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by: RemedyRepack Inc., Indiana, PA15701, 1-724-465-8762

### **HEALTH SENSE ASPIRIN 81**

aspirin tablet, coated

| Product Information   |   |                    |                                  |                   |
|---|---|--------------------|----------------------------------|-------------------|
| Product T ype   | HUMAN OTC DRUG  | Item Code (Source) | e) NDC:70518-0923(NDC:62107-027) |                   |
| Route of Administration   | ORAL  |                    |                                  |                   |
|   |   |                    |                                  |                   |
| Active Ingredient/Active Moi  | ety   |                    |                                  |                   |
| Ingredient Name   |   |                    | Basis of Strength                | Strength          |
| SPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) ASPIRIN   |   |                    |                                  |                   |
|   | N - UNII:R16CO5Y/6E)  | A                  | SPIRIN                           | 81 mg             |
| Inactive Ingredients  |   |                    | SPIRIN                           |                   |
| Inactive Ingredients  | Ingredient Nat  |                    | SPIRIN                           | 81 mg<br>Strength |
| Inactive Ingredients<br>FERROSOFERRIC OXIDE (UNII: XM0  | Ingredient Nat  |                    | SPIRIN                           |                   |
| Inactive Ingredients<br>Ferrosoferric oxide (UNII: XM0<br>STARCH, CORN (UNII: 08232NY3SJ)   | <b>Ingredient Nat</b><br>M87F357)                                   |                    | SPIRIN                           |                   |
| Inactive Ingredients<br>Ferrosoferric oxide (UNII: XM0<br>STARCH, CORN (UNII: 08232NY3SJ)   | <b>Ingredient Nat</b><br>M87F357)                                   |                    | SPIRIN                           |                   |
| Inactive Ingredients<br>FERROSOFERRIC OXIDE (UNII: XM0<br>STARCH, CORN (UNII: 08232NY3SJ)<br>D&C YELLOW NO. 10 (UNII: 35SW5U  | <b>Ingredient Nat</b><br>M87F357)<br>ISQ3G)                         |                    | SPIRIN                           |                   |
| Inactive Ingredients<br>FERROSOFERRIC OXIDE (UNII: XM0<br>STARCH, CORN (UNII: 08232NY3SJ)<br>D&C YELLOW NO. 10 (UNII: 35SW5U<br>FD&C YELLOW NO. 6 (UNII: H77VEIS                                  | Ingredient Nat<br>M87F357)<br>(SQ3G)<br>93A8)                       |                    | S PIRIN                          |                   |
| Inactive Ingredients<br>FERROSOFERRIC OXIDE (UNII: XM0<br>STARCH, CORN (UNII: 08232NY3SJ)<br>D&C YELLOW NO. 10 (UNII: 35SW5U<br>FD&C YELLOW NO. 6 (UNII: H77VEIS<br>HYPROMELLOSES (UNII: 3NXW29V3 | Ingredient Nat<br>M87F357)<br>ISQ3G)<br>93A8)<br>WO)                |                    | S PIRIN                          |                   |
|   | <b>Ingredient Nat</b><br>M87F357)<br>(SQ3G)<br>93A8)<br>WO)<br>656) |                    | SPIRIN                           |                   |



QTY: 30

Expires: Shape: Round Ref #: 62107-0027-32

| POLYETHYLENE GLY        | POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |   |                      |                    |  |  |  |  |
|-------------------------|---|---|----------------------|--------------------|--|--|--|--|
| PROPYLENE GLYCO         |   |   |                      |                    |  |  |  |  |
| SHELLAC (UNII: 46 N10   |   |   |                      |                    |  |  |  |  |
| SILICON DIO XIDE (U     |   |   |                      |                    |  |  |  |  |
| DIMETHICO NE (UNII:     |   |   |                      |                    |  |  |  |  |
| SODIUM BICARBONA        |   |   |                      |                    |  |  |  |  |
| SODIUM LAURYL SU        |   |   |                      |                    |  |  |  |  |
| TALC (UNII: 7SEV7J4F    |   |   |                      |                    |  |  |  |  |
| TITANIUM DIO XIDE (     | UNII: 15FIX9V2JP)                                   |   |                      |                    |  |  |  |  |
| TRIACETIN (UNII: XH)    | (3C3X673)   |   |                      |                    |  |  |  |  |
| TRIETHYL CITRATE        |   |   |                      |                    |  |  |  |  |
|                         |   |   |                      |                    |  |  |  |  |
|                         |   |   |                      |                    |  |  |  |  |
| Product Characteristics |   |   |                      |                    |  |  |  |  |
| Color                   | yello w   | Score   | no                   | no score           |  |  |  |  |
| Shape                   | ROUND   | Size  | 6 n                  | 6 m m              |  |  |  |  |
| Flavor                  |   | Imprint Code  | L                    | L                  |  |  |  |  |
| Contains                |   |   |                      |                    |  |  |  |  |
|                         |   |   |                      |                    |  |  |  |  |
|                         |   |   |                      |                    |  |  |  |  |
| Packaging               |   |   |                      |                    |  |  |  |  |
| # Item Code             | Packag  | Package Description                                 |                      | Marketing End Date |  |  |  |  |
| 1 NDC:70518-0923-       |   | n 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |  |  |  |  |
| <b>1</b> 0              | 50 III I DEISTER FACR, I                            | ype 0. Not a Combination Floduct                    | 12/20/2017           |                    |  |  |  |  |
|                         |   |   |                      |                    |  |  |  |  |
|                         |   |   |                      |                    |  |  |  |  |
| Marketing Information   |   |   |                      |                    |  |  |  |  |
| Marketing Category      |   |   | Marketing Start Date | Marketing End Date |  |  |  |  |
| OTC monograph final     | part343   |   |                      | <u> </u>           |  |  |  |  |
|                         | -   |   |                      |                    |  |  |  |  |

Labeler - REMEDYREPACK INC. (829572556)

Revised: 5/2020

REMEDYREPACK INC.