VALUE PHARMA ASPIRIN PAIN RELIEVER- as pirin tablet Ajes Pharmaceuticals, LLC

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.

DRUG FACTS

ASPIRIN

Purpose

Pain Reliever

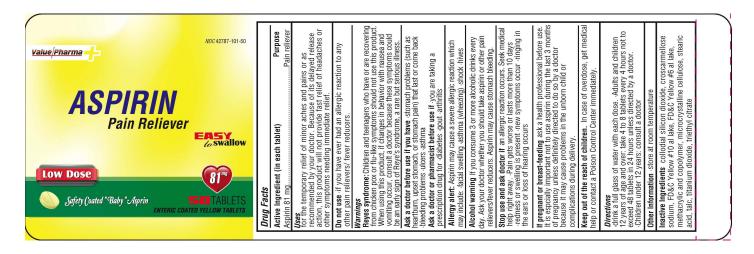
Inactive Ingredients

In case of over dose get medical help and contact a Poison Control Center immediately.

For temporary relief of minor aches and pains or as recommended by your Doctor. Because of this products delayed release action, this product will not provide fast relief of headaches or symptoms needing immediate relief.

Do not use if you have ever had an allergic reaction to any other pain relievers/fever reducers. Children or teenagers who are recovering from the Chicken Pox or flu like symptoms should not use this product. When using this product if changes in behavior occur with nausea and vomiting occur, consult a Doctor because this could be a sign of Reye's Syndrome, a rare but serious illness.

Directions - drink a full glass of water with each dose. Adults and children 12 years of age and over: take 4 to 8 tablets every 4 hours not to exceed48 tablets in 24 hours unless directed by a doctor. Children under 12 years: consult a doctor



| VALUE PHARMA ASPIRIN PAIN RELIEVER aspirin tablet | | | |
|---|----------------|--------------------|---------------|
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42787-101 |
| Route of Administration | ORAL | | |
| | | | |
| | | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 81 mg in 81 mg | |

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | | |
| CROSCARMELLOSE SODIUM (UNII: M28 O L1HH48) | | | |
| CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | | | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | |
| TALC (UNII: 7SEV7J4R1U) | | | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | | | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | | | |

| Product Characteristics | | | |
|-------------------------|-----------------------|--------------|----------|
| Color | yellow (Yellow color) | Score | no score |
| Shape | ROUND (Round Pill) | Size | 6 mm |
| Flavor | | Imprint Code | C3 |
| Contains | | | |

| Packaging | | | |
|--------------------|--|-----------------------------|---------------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:42787-101-50 | 1 in 1 CARTON | 10 / 0 1 / 20 12 | |
| 1 | 4050 mg in 1 BOTTLE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part343 | 10/01/2012 | |
| | | | |

Labeler - Ajes Pharmaceuticals,LLC (159945393)

| Establishment | | | | |
|--------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Ajes Pharmaceuticals,LLC | | 159945393 | manufacture(42787-101) | |

Revised: 12/2018 Ajes Pharmaceuticals,LLC