

ACIDO ACETILSALICILICO WITH ENTERIC COAT- aspirin tablet, coated

4Medical Group LLC

OTC Label - Aspirin - Allegiant Health



ACIDO ACETILSALICILICO WITH ENTERIC COAT
 aspirin tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83337-232(NDC:69168-405) |
| 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 |
|--|-----------------|
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| BROWN IRON OXIDE (UNII: 1N032N7MFO) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SODIUM HYDRIDE (UNII: 23J3BHR95O) | |
| D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6) | |
| METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | yellow | 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:83337-232-24 | 40 in 1 BOX; Type 0: Not a Combination Product | 07/03/2023 | |



Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| Export only | | 07/03/2023 | |

Labeler - 4Medical Group LLC (067443990)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|--------------------|--|-----------|--------------------|
| 4Medical Group LLC | | 067443990 | relabel(83337-232) |
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Revised: 7/2023

4Medical Group LLC