

PAIN FREE- acetaminophen, aspirin, caffeine, salicylamide tablet
Afasso 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.

Drug Facts

Active Ingredients (In Each Tablet)

Acetaminophen 110 mg, Aspirin 162 mg, Caffeine 32.4 mg, Salicylamide 152 mg

Pain reliever, Stimulant

Uses: For the temporary relief of pain from:

- headaches • colds • muscular aches
- menstrual cramps • toothaches
- minor arthritic pain • backaches

Warnings:

Reye's Syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's Syndrome, a rare but serious illness reported to be associated with aspirin.

Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take more than 8 tablets in 24 hours, with other drugs containing acetaminophen (prescription or non-prescription), or have 3 or more alcoholic drinks every day while using this product.

Stomach Bleeding Warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, are age 60 or older, have 3 or more alcoholic drinks every day while using this product, take with other drugs containing an NSAID, or take more or for a longer time than directed.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children.

Directions:

Adults and children: (12 years and older) Take 1 to 2 tablets with a full glass of water every 4 hours as needed. Do not exceed 6

tablets in 24 hours, or as directed by doctor.

Children: (under 12 years) Do not give to children under 12 years of age

SEE ORIGINAL BOX FOR COMPLETE PRODUCT INFORMATION



PAIN FREE

2 Tablets

Active Ingredients (In Each Tablet) Purposes

| | | |
|---------------|---------|--------------------|
| Acetaminophen | 110 mg |Pain Reliever |
| Aspirin | 162 mg |Pain Reliever |
| Caffeine | 32.4 mg |Stimulant |
| Salicylamide | 152 mg |Pain Reliever |

Uses: For the temporary relief of pain from:

- headaches
- colds
- muscular aches
- menstrual cramps
- toothaches
- minor arthritic pain
- backaches

Warnings:

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Questions? Contact Afassco Minden, NV 89423
Store at room temperature.

Tamper evident: Do not use packet if torn or cut.

Warnings (continued)

other drugs containing acetaminophen (prescription or non-prescription), or have 3 or more alcoholic drinks every day while using this product.

Stomach Bleeding Warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, are age 60 or older, have 3 or more alcoholic drinks every day while using this product, take with other drugs containing an NSAID, or take more or for a longer time than directed.

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PAIN FREE

acetaminophen, aspirin, caffeine, salicylamide tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51532-0242 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 110 |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 162 |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 32.4 |
| SALICYLAMIDE (UNII: EM8BM710ZC) (SALICYLAMIDE - UNII:EM8BM710ZC) | SALICYLAMIDE | 152 |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | orange | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | | Imprint Code | FR2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:51532-0242-2 | 2 in 1 PACKET; Type 0: Not a Combination Product | 10/25/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 10/25/2016 | |

Labeler - Afassco Inc. (609982723)