

**EXTRA STRENGTH PAIN RELIEVER- extra strength pain reliever tablet**  
**Redicare 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.*

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**Pain Reliever**

**Active Ingredient**

Acetaminophen 110 mg .....pain  
reliever/fever reducer

Aspirin 162 mg .....pain  
reliever/fever reducer

Caffeine 32.4  
mg.....adjuvant

Salicylamide 152 mg.....pain  
reliever/fever reducer

**Uses:**

temporarily relieves minor aches and pains associated with ■ headaches ■ colds ■ a toothache ■ minor arthritis pain ■ muscular aches ■ menstrual cramps ■ a backache

**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 ■ you take with other drugs containing acetaminophen (prescription or non-prescription) ■ you have 3 or more alcoholic drinks every day while using this product.

**Stomach Bleeding Warning:**

This product contains a non-steroidal anti-inflammatory drug (NSAIDs), 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 a NSAID ■ you take more or for a longer time than directed.

**Do not use:**

■ if you are allergic to aspirin ■ with any other pain reliever/fever reducer ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor ■ with any other product containing acetaminophen

**Ask doctor before using if you have:**

■ asthma ■ stomach problems (such as heartburn, upset stomach or stomach pain) ■ gastric ulcers ■ bleeding problems

**Ask a doctor or pharmacist before use if**

you are taking a prescription drug for ■ anticoagulation (thinning of blood) ■ diabetes ■ gout ■ arthritis

**When using this product do not exceed recommended dose.****Stop use and ask a doctor if**

■ ringing in the ears or loss of hearing occurs • pain or fever persists or gets worse ■ new symptoms occur ■ redness or swelling is present

**If pregnant or breast-feeding a baby,**

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 a case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions:**

Adults and children 12 years of age and older: Take 2 tablets every 4 hours as needed, with a full glass of water. Do not exceed 6 tablets in any 24 hour period  
Children under 12 years: Ask a doctor

**Other Information:**

■ Tamper Evident. Do not use if packet is torn, cut or opened ■ Store at controlled room temperature 15° to 30°C (59° to 86°F) ■ Avoid excessive heat and humidity

## Inactive Ingredients:

FD&C Yellow #6, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, starch and stearic acid



## EXTRA STRENGTH PAIN RELIEVER

extra strength pain reliever tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71105-242
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	orange (Rose Orange)	<b>Score</b>	no score
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<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	FR2
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71105-242-68	100 in 1 CARTON; Type 0: Not a Combination Product	10/01/2017	



**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part343	10/01/2017	
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**Labeler -** Redicare LLC (800149346)

Revised: 7/2021

Redicare LLC