

PAIN RELIEVER 2- 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.

Advanced Pain Reliever

Active Ingredients (in each tablet)

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

Purpose

pain reliever/fever reducer, adjuvant

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 chickenpox 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 an 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 ■ with large amounts of caffeinated products

Ask a doctor before use if you have:

■ asthma, liver, kidney, high blood pressure or heart disease ■ stomach problems (such as heartburn, upset or painful stomach) ■ gastric ulcers ■ bleeding problems ■ taking a diuretic ■ or if the stomach bleeding warning applies to you

Ask a doctor or pharmacist before use if

you are taking a prescription drug for ■ anticoagulation (thinning of blood) ■ diabetes ■ gout ■ arthritis ■ with other drugs or conditions

When using this product

do not exceed the recommended dose.

Stop use and ask a doctor if:

■ ringing in the ears or loss of hearing occurs ■ pain or fever persists or worsens ■ new symptoms occur ■ allergic reaction, 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 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 6 hours as needed, with a full glass of water. Do not exceed 8 tablets in any 24 hour period

Children under 12 years: Ask a doctor

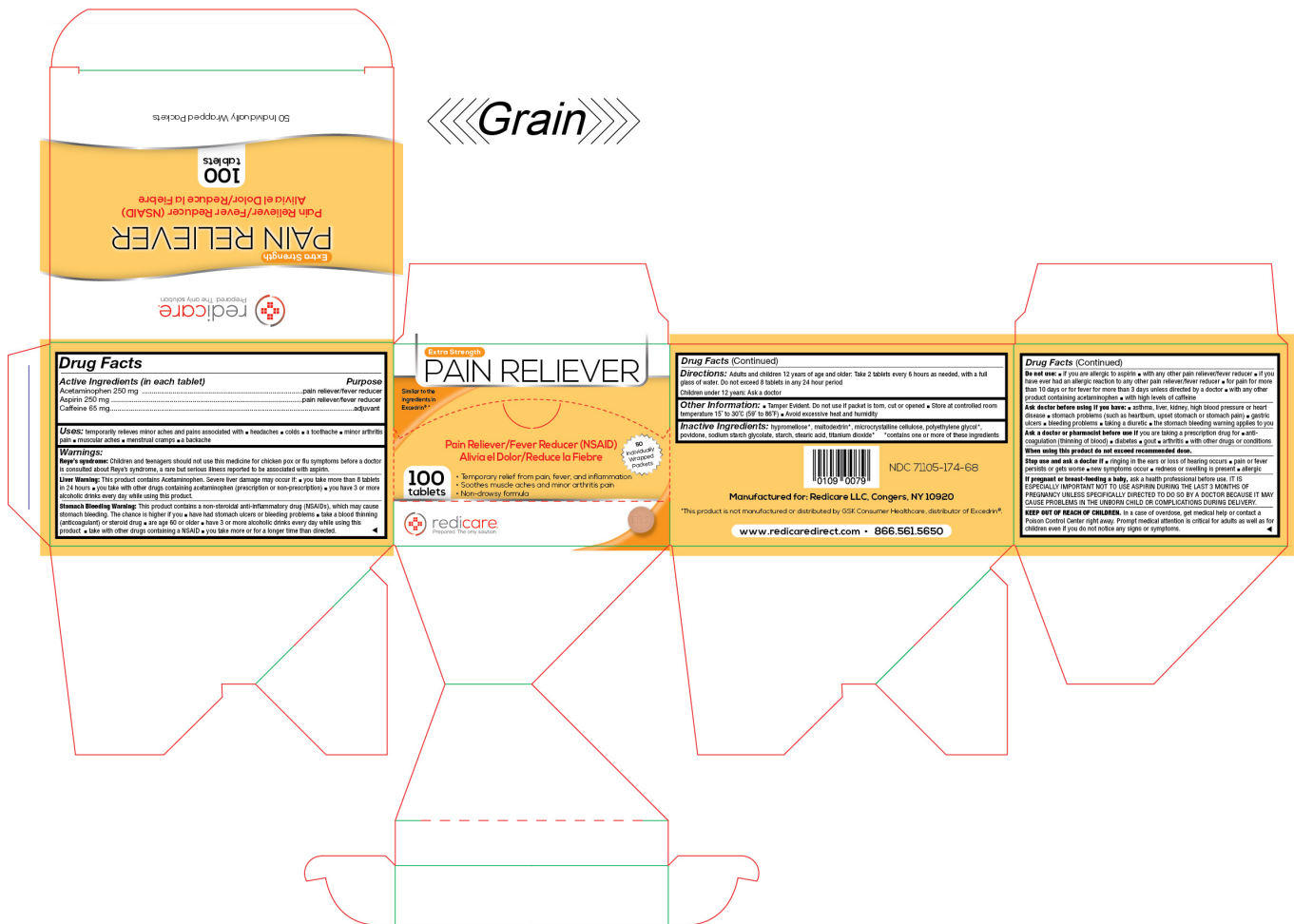
Other Information:

■ Tamper Evident. Do not use if a 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:

hypromellose*, maltodextrin*, microcrystalline cellulose, polyethylene glycol*, povidone, sodium starch glycolate, starch, stearic acid, titanium dioxide*

*contains one or more of these ingredients



PAIN RELIEVER 2			
pain reliever tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71105-174
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
	ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
	CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (50 MPA.S) (UNII: 1IVH67816N)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	fr9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71105-174-68	50 in 1 BOX	01/03/2020	
1	NDC:71105-174-02	2 in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/03/2020	

Labeler - Redicare LLC (800149346)

Revised: 7/2021

Redicare LLC