PAIN AND SINUS RELIEVER- acetaminophen and phenylephrine tablet
ADVANCED FIRST AID, 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.

Pain & Sinus Reliever

ACTIVE INGREDIENT IN EACH TABLET-

Acetaminophen 500 mg

Phenylephrine HCl 5 mg

pain reliever/fever reducer

decongestant

Uses: temporarily: • relieves nasal congestion associated with sinusitis • relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies • relieves sinus congestion and pressure, helps decongest sinus openings and passages • restores freer breathing

temporarily relieves minor aches, pains, and fever associated with: • headache • common cold • toothache • backache • muscular aches • menstrual cramps

Warnings:

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

Alergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash • If a skin reaction occurs, stop use and seek medical help right away.

Do not use:

• with any other product containing acetaminophen this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns.

• more than the recommended dose

• for more than 10 days for pain unless directed by a doctor

• for more than 3 days for fever unless directed by a doctor

• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this prouct.

Ask a doctor or pharmacist before use if: • you are taking the blood thinning drug warfarin.

Stop use and ask a doctor if:

• symptoms do not improve • pain or fever persists or gets worse • new symptoms occur • redness or swelling is present • nervousness, dizziness or sleeplessness occur • symptoms do not improve within 7 days or are accompanied by fever

Ask a doctor before use if you have: • heart disease • liver disease •high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland

When using this product do not exceed recommended dose.

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

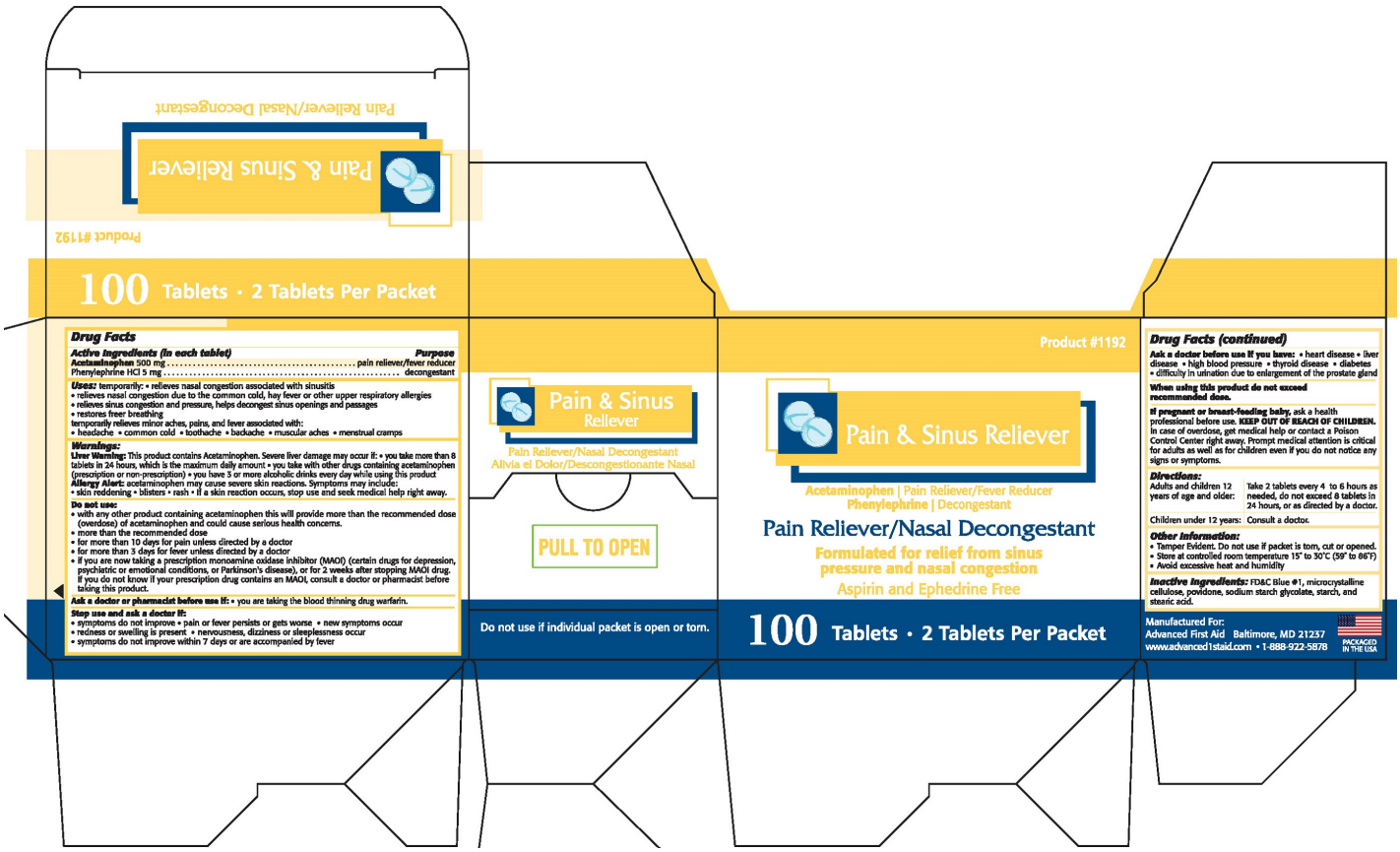
KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

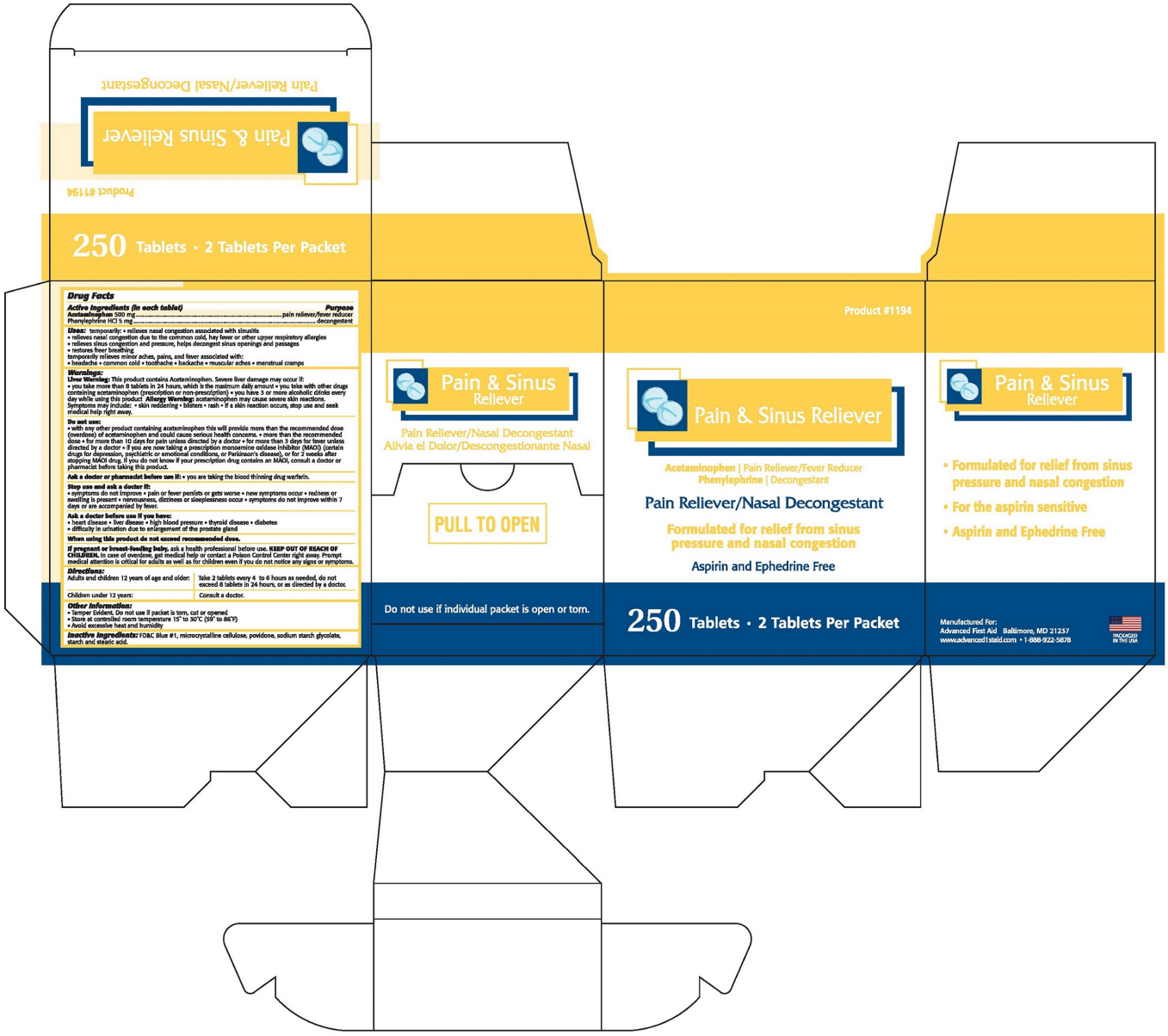
Directions:

Adults and children 12 years of age and older: Take 2 tablets every 4 to 6 hours or as needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor.

Children under 12 years: Consult a doctor.

Inactive Ingredients: FD&C Blue #1, microcrystalline cellulose, povidone, sodium starch glycolate, starch, and stearic acid.





PAIN AND SINUS RELIEVER

acetaminophen and phenylephrine tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67060-194
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	blue (LIGHT BLUE)	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	FR33
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67060-194-68	100 in 1 CARTON	04/09/2015	08/01/2024
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67060-194-67	250 in 1 CARTON	04/09/2015	08/01/2024
2		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/09/2015	08/01/2024

Labeler - ADVANCED FIRST AID, INC. (114477180)

Registrant - ADVANCED FIRST AID, INC. (114477180)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(67060-194)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA TAB LABORATORIES, INC.		151051757	manufacture(67060-194)