

**SANAFLU XTRA- acetaminophen, chlorpheniramine maleate,
dextromethorphan hydrobromide, phenylephrine hydrochloride capsule,
gelatin coated
GRANDALL DISTRIBUTING, LLC**

Grandall (as PLD) - Sanaflu Xtra (48201-001)

Active ingredients (in each capsule)

Acetaminophen 250 mg

Chlorpheniramine maleate 2 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever - fever reducer

Antihistamine

Cough Suppressant

Nasal Decongestant

Uses

- Temporarily relieves
- minor aches and pains
- headache
- runny nose
- sneezing
- nasal congestion
- itchy, watery eyes due to hay fever or other upper respiratory allergies
- itching of the nose or throat
- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- Temporarily reduces fever

Warnings

Liver warning This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- heart disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm
- thyroid disease
- diabetes

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- may cause marked drowsiness
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- may cause excitability, especially in children.

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- nervousness, dizziness, or sleeplessness occur.

If pregnant or breast-feeding,

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 even if you do not notice any signs or symptoms.

Directions

- Adults and children 12 years of age and older: Take 2 capsules every 4 hours; not more than 12 capsules in 24 hours.
- Children under 12 years of age: Consult a doctor.

Other information

- Store at room temperature in a dry place.

Inactive ingredients

D&C Red 33, FD&C Blue 1, gelatin, glycerin, polyethylene glycol 600, polyethylene glycol 1000, polyvinylpyrrolidone, propylene glycol, sodium methylparaben, sodium propylparaben, water

Package Labeling

The image shows the front of a Sanaflu Xtra Adult Flu and Cough softgel blister pack. The packaging is primarily blue and white. At the top, it says "Adult Flu and Cough" in red and white. The brand name "sanaflu" is written in large, bold, blue letters with a white outline, and "Xtra" is in red. Below the name, the ingredients are listed: Acetaminophen (Pain Reliever - Fever Reducer), Chlorpheniramine Maleate (Antihistamine), Dextromethorphan HBr (Cough Suppressant), and Phenylephrine (Nasal Decongestant). At the bottom, there are three softgels shown, with the text "12 softgels" in a blue oval. On the right side, there is a barcode with the number 48201 01814 2 and the text "DISTRIBUTED BY: GRANDALL DIST. CO., INC. GLENDALE, CA 91204 1-800-344-2422 www.grandall.com MADE IN MEXICO". On the left side, there is a tamper-evident seal and a "Keep this carton - it has complete information." label.

Adult Flu and Cough

sanaflu[®]

Xtra

Acetaminophen
Pain Reliever - Fever Reducer

Chlorpheniramine Maleate
Antihistamine

Dextromethorphan HBr
Cough Suppressant

Phenylephrine
Nasal Decongestant

Flu
Cough
Fever

Aches and pains
Nasal congestion
Runny nose

12 softgels

Tamper-evident: do not use if any blister unit is torn, broken, or shows any sign of tampering.

Batch #

Exp. Date

Keep this carton - it has complete information.

3 48201 01814 2

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GLENDALE, CA 91204
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MADE IN MEXICO

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Drug Facts (continued)

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SANAFLU XTRA

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48201-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue (transparent blue)	Score	no score
Shape	OVAL (oblong)	Size	24mm
Flavor		Imprint Code	none
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48201-001-12	12 in 1 BOX; Type 0: Not a Combination Product	04/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/30/2015	

Labeler - GRANDALL DISTRIBUTING, LLC (044428324)

Revised: 1/2024

GRANDALL DISTRIBUTING, LLC