

**SANATOS X- acetaminophen, dextromethorphan hbr, guaifenesin,
phenylephrine hci liquid
Pharmadel LLC**

SanaTos X Fast Action (PLE)(APTA)

Drug Facts

Active ingredients and Purposes

Active ingredients (in each 20 mL)	Purposes
Acetaminophen 650mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg.....	Nasal decongestant

Uses

- temporarily relieves these common cold/ flu symptoms:
- minor aches and pains
- headache
- sore throat
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- make coughs more productive
- nasal congestion
- stuffy nose
- hay fever
- temporarily reduces fever

Warnings

Liver warning:

This product contains **acetaminophen**.

Severe liver damage may occur if you:

- take more than 6 doses in 24 hours, which is the maximum daily amount
- take with other drugs containing acetaminophen
- have 3 or more alcoholic drinks every day while using this product

Allergy alert:

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening

- blisters
- rash If an allergic reaction occurs, stop use and seek medical help right away.

Sore throat warning:

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly.

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 or your child 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 child's or your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

Ask a doctor before use if you have

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

Stop use and ask a doctor if

- skin rash appears
- symptoms persist for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache.
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- nervousness, dizziness, or sleeplessness occur

These could be signs of a serious condition.

If pregnant or breastfeeding,

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

- **do not take more than directed**
- dosing cup included
- do not take more than 6 doses in any 24-hour period
- this product is not intended for use in children under 12 years of age

age	dose
adults & children 12 years of age & over	20 mL every 4 hours
children under 12 years of age	do not use

Other information

- each 20 mL contains: sodium 10 mg
- store at 59-86°F (15-30°C)
- do not refrigerate

TAMPER EVIDENT FEATURE: Do not use if printed seal under cap is torn or missing.

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions or comments?

1-866-359-3478 (M-F) 9 AM to 5 PM EST or www.pharmadel.com

Principal Display Panel

MAXIMUM STRENGTH • MÁXIMA POTENCIA

SANATOS® X

FAST ACTION/ACCIÓN RÁPIDA

ACETAMINOPHEN Dextromethorphan HBr, Guaifenesin, Phenylephrine
HCl/ACETAMINOFÉN Dextrometorfano HBr,
Guaifenesina, Fenilefrina HCl

COUGH, COLD & SORE THROAT/TOS, RESFRIADO y DOLOR DE GARGANTA

Fever/Fiebre

Aches and pains/Dolores y molestias leves

Headache/Dolor de Cabeza

Expectorant/Expectorante

Nasal decongestant/Descongestivo Nasal

For ages 12+/Para edades 12+

6 fl oz (177 mL)

Drug Facts (continued)

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 children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed
- dosing cap included
- do not take more than 6 doses in any 24-hour period
- this product is not intended for use in children under 12 years of age

age	dose
adults & children 12 years of age & over	20 mL every 4 hours
children under 12 years of age	do not use

Other information

each 20 mL contains acetaminophen 10 mg & pseudoephedrine HCl 10 mg (15-30°C) & do not refrigerate. TAMPER EVIDENT FEATURE: Do not use if printed seal under cap is torn or missing.

Inactive ingredients

ethylene glycol, citric acid, & citrate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions or comments?

1-866-359-3478 (M-F) 9 AM to 5 PM EST or www.pharmadel.com

Datos Farmacéuticos

Ingredientes activos

Ingredientes activos	Propósitos
Acetaminofeno 10 mg	Alivio del dolor y fiebre
Dextrometorfano HCl 10 mg	Supresión de la tos
Guafenesina 400 mg	Expectorante
Fenilefrina HCl 10 mg	Descongestionante nasal

Uso

- Tome puntualmente según las indicaciones con o sin el refresco/gelato.
- dolor y dolores leves = dolor de cabeza = dolor de garganta
- los dolores de la infección leve de la garganta y bronquitis
- ayuda a aliviar la fiebre (resaca) y las secreciones bronquiales para drenar los tubos bronquiales
- resaca que le ha causado resaca = congestión nasal
- nariz tapada = fiebre del lino
- Tome puntualmente reduce la fiebre

Advertencias

Advertencia del hígado: Este producto contiene a Acetaminofeno. Dosis excesivas pueden causar daño al hígado. Si ocurre una reacción alérgica, para el uso y busque ayuda médica de inmediato.

Advertencia para el dolor de garganta: Un dolor de garganta severo o persistente o dolor de garganta acompañado de fiebre alta, dolor de cabeza, náuseas y vómitos puede ser grave. Consulte con un médico inmediatamente.

No utilice con cualquier otro medicamento que contenga acetaminofeno (con o sin refresco). Si no está seguro de si el medicamento contiene acetaminofeno, pregúntele a su médico o a su farmacéutico. Si usted o su hijo están tomando un inhibidor de la monoaminoxidasa (IMAO) recetado (para los medicamentos para la depresión, parkinsonismo o enfermedad de Parkinson), o durante 2 semanas después de suspender el medicamento IMAO. Si no está si el medicamento recetado de su hijo o si de edad contiene un IMAO, consulte a un médico o farmacéutico antes de tomar este producto.

Pregúntele a un médico o farmacéutico antes de usar si está tomando el medicamento anticoagulante warfarina.

Datos Farmacéuticos (continúa)

Pregúntele a un médico antes de usar el refresco si tiene: enfermedad hepática = presión arterial alta = una tos que se acompaña con fiebre o náuseas (resaca) = los parásitos o crías, como ocurre con el botulismo, el sarampión, la bronquitis o el síndrome = dificultad para orinar debido al agrandamiento de la glándula prostática = enfermedad cardíaca = estreñimiento de la triada = diabetes

Deje de usar y pregúntele a un médico si: aparece una ampolla en la piel = aparecen unas ampollas en la piel = los síntomas persisten después de más de 7 días, tiende a ocurrir, o se acompaña de fiebre, erupción de la piel o dolor de cabeza persistente = la fiebre aparece o dura más de 3 días

Si está embarazada o lactando, pregúntele a un profesional de la salud antes de usar.

Manténgase fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o póngase en contacto con un Centro de Control de Envenenamiento (1-800-525-0247). La observación médica inmediata es crítica tanto para adultos como para niños, incluso si no se observan signos o síntomas.

Instrucciones

- no tome más de lo indicado
- tasa de dosificación incluida
- no tome más de 6 Dosis en cualquier período de 24 horas
- este producto no se usa en niños menores de 12 años de edad

edad	dosis
adultos & niños 12 años de edad y más	20 mL cada 4 horas
niños menores de 12 años de edad	no utilice

Otra información

cada 20 mL contiene acetaminofeno 10 mg & pseudoephedrine HCl 10 mg (15-30°C) & no refrigerar

EVIDENCIA DE MANIPULACIÓN: No utilice si el sello impreso debajo de la tapa está roto o faltante.

Ingredientes inactivos: agua destilada, FD&C azul no. 1, FD&C rojo no. 40, saborizante, glicerina, propilenglicol, jaleo de propilo, agua purificada, bencato de sodio, acetato, sucralosa, goma xantana.

¿Preguntas o comentarios?

1-866-359-3478 (L-V) 9 AM a 5 PM Este o www.pharmadel.com

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PHARMDEL, LLC
Georgetown, DE 19947

SanaTos^X

FAST ACTION
ACCIÓN RÁPIDA

MAXIMUM STRENGTH • MÁXIMA POTENCIA

NDC 0078-311-08

SanaTos^X

FAST ACTION
ACCIÓN RÁPIDA

ACETAMINOPHEN Dextromethorphan HCl,
Guafenesina, Phenylephrine HCl

ACETAMINOFEN Dextrometorfano HCl,
Guafenesina, Fenilefrina HCl

COUGH, COLD & SORE THROAT

TOS, RESFRIADO y DOLOR DE GARGANTA

- ✓ Fiebre
- ✓ Dolores y molestias leves
- ✓ Dolor de Cabeza
- ✓ Expectorante
- ✓ Descongestivo Nasal
- ✓ Headache
- ✓ Expectoant
- ✓ Nasal decongestant
- ✓ Fiebre
- ✓ Dolores y molestias leves
- ✓ Dolor de Cabeza
- ✓ Expectorante
- ✓ Descongestivo Nasal



For ages 12+
Para edades 12+

6 fl oz (177 mL)

BX-079



Drug Facts

Active ingredients (in each 20 mL) Purposes

Acetaminophen 10 mg Pain reliever/fever reducer
Dextromethorphan HCl 10 mg Cough suppressant
Guafenesina 400 mg Expectorant
Phenylephrine HCl 10 mg Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
 - runny nose and sneezing
 - headache
 - sore throat
 - cough due to minor throat and bronchial irritation
 - helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
 - nasal congestion
 - stuffy nose
 - hay fever
 - temporarily reduces fever

Warnings

Use warnings: This product contains acetaminophen. Severe liver damage may occur if you: take more than 6 doses in 24 hours, which is the maximum daily amount

take with other drugs containing acetaminophen or take 3 or more alcoholic drinks every day while using this product.

Always alert: Acetaminophen may cause severe side reactions. Symptoms may include: skin redness = hives = rash

If an allergic reaction occurs, stop use and seek medical help right away.

Sore throat warnings: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly.

Do not use with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. If you or your child are now taking a prescription medication outside the United States (including antidepressants, antipsychotics, or sedatives), or if you are taking the MAOI drug, ask a doctor or pharmacist before taking this product.

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

Ask a doctor before use if you have a liver disease = high blood pressure = a cough that is accompanied with excessive phlegm (mucus) = persistent or chronic cough such as occurs with smoking, asthma, bronchitis, or emphysema = difficulty in urination due to enlargement of the prostate gland = heart disease = thyroid disease = diabetes

Stop use and ask a doctor if: a rash appears = symptoms persist for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache.

Severe gets worse or lasts more than 3 days = weakness or swelling in the lower leg = a new symptom occurs = irritation, dizziness, or sleepiness occur These could be signs of a serious condition.

If pregnant or breastfeeding, ask a health professional before use.

SANATOS X

acetaminophen, dextromethorphan hbr, guafenesin, phenylephrine hci liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55758-311

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0K00R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-311-06	1 in 1 BOX	12/03/2018	
1		1 in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/03/2018	

Labeler - Pharmadel LLC (030129680)