

**XL-3 DAY TIME- acetaminophen, dextromethorphan hbr, phenylephrine
hcl liquid
AptaPharma Inc.**

XL-3* Day Time

Drug Facts

**Active ingredients
(in each 15 mL, 1 tablespoon)**

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough Suppressant
Nasal decongestant

Uses

temporarily relieves common cold and flu symptoms:
• nasal congestion • cough due to minor throat and bronchial
irritation • sore throat • headache • minor aches and pains • fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if
• adult takes more than 4,000 mg of acetaminophen in 24 hours • child takes more than
5 doses in 24 hours • taken with other drugs containing acetaminophen • adult has 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 a skin reaction occurs,
stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, lasts for more than 2 days, is
accompanied or followed by fever, headache, rash, nausea, or vomiting,
consult a doctor promptly.

Do not use

• with any other products containing acetaminophen (prescription or nonprescription). If
you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist •
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 the MAOI drugs. 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
- heart disease • thyroid disease • diabetes • high blood pressure
- trouble urinating due to enlarged prostate gland • cough accompanied by excessive phlegm (mucus) • persistent or chronic cough such as occurs with smoking, asthma, or emphysema.

Ask a doctor or pharmacist before use

if you are taking the blood thinning drug warfarin

When using this product

- do not use more than directed (see overdose warning) • avoid alcoholic drinks

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms get worse or last more than 5 days (children) or 7 days (adults)
- 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.

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

Keep out of reach of children.

Overdose warning:

Taking more than the recommended dose (overdose) may cause serious health problems including liver damage. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions • take only as directed - see Overdose warning

- use dose cup or tablespoon • do not exceed 4 doses per 24 hours
- if taking Day Time during the day and Night Time at night, limit total to 4 doses per 24 hours

adults & children 12 years and over	30 mL (2 TBSP) every 4 hours
children 6 to under 12 years	15mL (1TBSP) every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

Other information

- Sodium content per tablespoon: 10mg
- store at 20°-25°C (68°-77° F).

Inactive ingredients

citric acid, FD & C Yellow No.6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucrose.

Questions or Comments?

Call weekdays from 9:30 AM to 4:30 PM EST
1-877-798-5944

Principal Display Package

XL-3[®] Day Time
Non-Drowsy Cold/Flu relief

COLD MEDICINE

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Phenylephrine HCl - Nasal Decongestant

Fast relief of:

- NASAL CONGESTION
- FEVER
- ACHES & PAINS
- SORE THROAT
- COUGH

Orange Flavor

12 FL OZ (354 mL)

XL-3[®] Day Time
Non-Drowsy Cold/Flu relief

COLD MEDICINE

- Acetaminophen - Pain Reliever/Fever Reducer
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Fast relief of:

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- COUGH

Orange Flavor

12 FL OZ (354 mL)

XL-3[®] Day Time
COLD MEDICINE

DO NOT USE IF PRINTED SHRINK BAND IS MISSING OR BROKEN
Failure to follow these warnings could result in serious consequences

Active ingredients (in each 15 mL, 1 tablespoon)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough Suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses: temporarily relieves common cold and flu symptoms:
• nasal congestion • cough due to minor throat and bronchial irritation • sore throat • headache • minor aches and pains • fever

DRUG FACTS CONTINUED ON BACK

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Midway Importing, Inc.
1807 Britton Road,
Houston, TX 77043 1-800-531-3873
Made in USA

LR-059 REV 03 Peel back

XL-3* Day Time

COLD MEDICINE

Drug Facts (continued)

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if • adult takes more than 4,000 mg of acetaminophen in 24 hours • child takes more than 5 doses in 24 hours • taken with other drugs containing acetaminophen • adult has 3 or more alcoholic drinks every day while using this product.

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

Sore throat warning: If sore throat is severe, lasts for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use • with any other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. • 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 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 • heart disease • thyroid disease • diabetes • high blood pressure • trouble urinating due to enlarged prostate gland • cough accompanied by excessive phlegm (mucus) • persistent or chronic cough such as occurs with smoking, asthma, or emphysema.

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

Drug Facts (continued)

When using this product • do not use more than directed (see overdose warning) • avoid alcoholic drinks

Stop use and ask a doctor if • you get nervous, dizzy or sleepless • symptoms get worse or last more than 5 days (children) or 7 days (adults) • 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.

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.**

Overdose warning: Taking more than the recommended dose (overdose) may cause serious health problems including liver damage. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions • take only as directed - see Overdose warning • use dose cup or tablespoon • do not exceed 4 doses per 24 hours • if taking Day Time during the day and Night Time at night, limit total to 4 doses per 24 hours

adults & children 12 years and over	30 mL (2 TBSP) every 4 hours
children 6 to under 12 years	15 mL (1 TBSP) every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

Other information • Sodium content per tablespoon 10 mg • store at 20°-25°C (68°-77°F).

Inactive ingredients: citric acid, FD & C Yellow No. 6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucrose.

Questions or Comments? Call weekdays from 9:00 AM to 4:00 PM EST 1-877-798-5944

XL-3* Day Time Non-Drowsy Cold/Flu relief

COLD MEDICINE

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Phenylephrine HCl - Nasal Decongestant

Fast Relief of:
NASAL CONGESTION
FEVER
ACHES & PAINS
SORE THROAT
COUGH

12 FL OZ (354 mL) Orange Flavor

XL-3* Day Time Non-Drowsy Cold/Flu relief

COLD MEDICINE

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FEVER
ACHES & PAINS
SORE THROAT
COUGH**

12 FL OZ (354 mL) Orange Flavor

XL-3* Day Time

COLD MEDICINE

DO NOT USE IF PRINTED SHRINK BAND IS MISSING OR BROKEN

Failure to follow these warnings could result in serious consequences

Drug Facts

Active ingredients

(in each 15 mL, 1 tablespoon)

Acetaminophen 325 mg Pain reliever/fever reducer
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Purpose

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→ DRUG FACTS CONTINUED ON BACK →

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Made in USA

LR-059 REV 03 Peel
back ►

XL-3* Day Time

COLD MEDICINE

Drug Facts (continued)

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Ask a doctor before use if you have • liver disease

• heart disease • thyroid disease • diabetes • high blood pressure
• trouble urinating due to enlarged prostate gland • cough accompanied by excessive phlegm (mucus) • persistent or chronic cough such as occurs with smoking, asthma, or emphysema.

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

Drug Facts (continued)

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Other information • Sodium content per tablespoon: 10mg
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XL-3*

Day Time

Non-Drowsy Cold/Flu relief

COLD MEDICINE

- **Acetaminophen - Pain Reliever/Fever Reducer**
- **Dextromethorphan HBr - Cough Suppressant**
- **Phenylephrine HCl - Nasal Decongestant**

Fast Relief of:

NASAL CONGESTION

FEVER

ACHES & PAINS

SORE THROAT

COUGH

6 FL OZ (177 mL)

Orange Flavor

XL-3[®] Day Time COLD MEDICINE

DO NOT USE IF PRINTED SHRINK BAND IS MISSING OR BROKEN
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Drug Facts

Active ingredients (in each 15 mL, 1 tablespoon) **Purpose**

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Non-Drowsy Cold/Flu relief

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- SORE THROAT
- FEVER
- COUGH
- ACES & PAINS

6 FL OZ (177 mL)

Orange Flavor

XL-3[®] Day Time COLD MEDICINE



LR-117

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1807 Brittmore Road,
Houston, TX
Made in USA

*Trademark

Peel back

XL-3[®] Day Time COLD MEDICINE

Drug Facts (continued)

24 hours • child takes more than 5 doses in 24 hours • taken with other drugs containing acetaminophen • adult has 3 or more alcoholic drinks every day while using this product.

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Drug Facts (continued)

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Inactive ingredients citric acid, FD & C Yellow No.6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucrose.

Questions or Comments? Call weekdays from 9:30 AM to 4:30 PM EST 1-877-798-5944

XL-3 DAY TIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-304
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg in 15 mL
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Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BEHENATE (UNII: H4W8BMK72F)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-304-28	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2018	

XL-3 DAY TIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-306
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BEHENATE (UNII: H4W8BMK72F)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-306-25	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/01/2018	

Labeler - Aptapharma Inc. (790523323)

Registrant - Aptapharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(76281-304, 76281-306)

Revised: 12/2023

Aptapharma Inc.