

**XL-3 XTREME- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid**  
**AptaPharma Inc.**

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**XL-3\* Xtreme Night Time Cold and Cough**

Drug Facts

**Active Ingredients**

(in each 30 mL dose cup)

Acetaminophen 650 mgr

Dextromethorphan HBr 30 mg

Doxylamine Succinate 12.5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Use**

temporarily relieves cold/flu symptoms: • sore throat  
headache • minor aches and pain • fever • runny nose and  
sneezing • cough due to minor throat and bronchial irritation

**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

**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, persists for more than two 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.

- to make a child sleepy.

### **Ask a doctor before use if you have**

- a sodium restricted diet • liver disease • glaucoma • cough that occurs with too much phlegm (mucus) • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland.

### **Ask a doctor or pharmacist before use**

- if you are taking sedatives or tranquilizers • if you are taking the blood thinning drug warfarin.

### **When using this product**

- **do not use more than directed** • avoid alcoholic drinks
- excitability may occur, especially in children • marked drowsiness may occur • be careful when driving a motor vehicle or operating machinery • alcohol, sedatives and tranquilizers may increase drowsiness.

### **Stop use and ask a doctor if**

- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days • new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, 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 recommended-see Overdose warning
- Use dose cup or tablespoon (TBSP) • do not exceed 4 doses per 24 hours • if taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours.

adults & children 12 years and over  
children 4 to under 12 years  
children under 4 years

30 mL (2 TBSP) every 6 hours  
ask a doctor  
do not use

## Other information

- each 30 mL dose cup contains: sodium 45 mg
- store at 20°-25°C (68°-77° F).

## Inactive ingredients

citric acid, FD & C Blue No.1, FD & C Red No. 40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose.

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

## XL-3 Xtreme Night Time Cold and Cough

**XL-3<sup>\*</sup>**  
**Cherry Flavor**  
**Night Time Xtreme**  
Multi-Symptom Cold/Flu Relief  
**Cold and Cough**

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

Fast relief of:

- SNEEZING & RUNNY NOSE
- FEVER
- ACHES & PAINS
- COUGH
- SORE THROAT

12 FL OZ (354 mL)

**XL-3<sup>\*</sup>**  
**Cherry Flavor**  
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Fast relief of:

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- FEVER
- ACHES & PAINS
- COUGH
- SORE THROAT

12 FL OZ (354 mL)

**XL-3<sup>\*</sup> Xtreme**  
**Cold and Cough**

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 30 mL dose cup)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine Succinate 12.5 mg	Antihistamine

**Uses** temporarily relieves cold/flu symptoms: • sore throat  
• headache • minor aches and pain • fever • runny nose and sneezing • cough due to minor throat and bronchial irritation

DRUG FACTS CONTINUED ON BACK

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LR-060 REV 03

Peel back

# XL-3\* Xtreme

## Cold and Cough

### Drug Facts (continued)

#### 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.

**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, persists for more than two 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 medication (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. • to make a child sleepy.

#### Ask a doctor before use if you have

• a sodium restricted diet • liver disease • glaucoma • cough that occurs with too much phlegm (mucus) • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema • trouble urinating due to enlarged prostate gland.

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

### Drug Facts (continued)

**When using this product** • do not use more than directed. • avoid alcoholic drinks • excitability may occur, especially in children • marked drowsiness may occur • be careful when driving a motor vehicle or operating machinery • alcohol, sedatives and tranquilizers may increase drowsiness.

**Stop use and ask a doctor if** • redness or swelling is present • symptoms do not get better within 7 days or are accompanied by a fever • fever gets worse or lasts more than 3 days • new symptoms occur • cough lasts more than 7 days, comes back, or occurs with fever, 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 recommended - see Overdose warning • Use dose cup or tablespoon (TBSF) • do not exceed 4 doses per 24 hours • if taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours.

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

**Other information** • each 30 mL dose cup contains sodium 45 mg • store at 20°-25°C (68°-77°F).

**Inactive ingredients** citric acid, FD & C Blue No. 1, FD & C Red No. 40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose.

**Questions or Comments?** Call week-days from 8:30 AM to 4:30 PM EST 1-877-786-5844

## XL-3\* Xtreme Cherry Flavor Night Time

### Multi-Symptom Cold/Flu relief

#### Cold and Cough

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

#### Fast Relief of:

#### SNEEZING & RUNNY NOSE

#### FEVER

#### ACHES & PAINS

#### COUGH

#### SORE THROAT

12 FL OZ (354 mL)

## XL-3\* Xtreme Cherry Flavor Night Time

### Multi-Symptom Cold/Flu relief

#### Cold and Cough

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

**Fast Relief of:**  
**SNEEZING & RUNNY NOSE**  
**FEVER**  
**ACHES & PAINS**  
**COUGH**  
**SORE THROAT**

**12 FL OZ (354 mL)**

**XL-3\* Xtreme**

**Cold and Cough**

**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 30 mL dose cup)**

Acetaminophen 650 mg ..... Pain reliever/fever reducer  
Dextromethorphan HBr 30 mg .....Cough suppressant  
Doxylamine Succinate 12.5 mg .....Antihistamine

**Purpose**

**Uses** temporarily relieves cold/flu symptoms: • sore throat  
headache • minor aches and pain • fever • runny nose and  
sneezing • cough due to minor throat and bronchial irritation

**→ DRUG FACTS CONTINUED ON BACK →**

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**XL-3\* Xtreme**

**Cold and Cough**

**Drug Facts** (continued)

**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

**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, persists for more than two 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.

• to make a child sleepy.

**Ask a doctor before use if you have**

• a sodium restricted diet • liver disease • glaucoma • cough that occurs with too much phlegm (mucus) • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema  
• trouble urinating due to enlarged prostate gland.

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

**Drug Facts** (continued)

**When using this product • do not use more than directed** • avoid alcoholic drinks • excitability may occur, especially in children • marked drowsiness may occur • be careful when driving a motor vehicle or operating machinery • alcohol, sedatives and tranquilizers may increase drowsiness.

**Stop use and ask a doctor if** • redness or swelling is present  
• symptoms do not get better within 7 days or are accompanied by a fever  
• fever gets worse or lasts more than 3 days • new symptoms occur  
• cough lasts more than 7 days, comes back, or occurs with fever, 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 recommended-see Overdose warning  
• Use dose cup or tablespoon (TBSP) • do not exceed 4 doses per 24 hours • if taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours.  
adults & children 12 years and over 30 mL (2 TBSP) every 6 hours  
children 4 to under 12 years ask a doctor  
children under 4 years do not use

**Other information** • each 30 mL dose cup contains: sodium 45 mg  
• store at 20°-25°C (68°-77° F).

**Inactive ingredients** citric acid, FD & C Blue No.1, FD & C Red No. 40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium

benzoate, sodium citrate, sucrose.

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



**XL-3<sup>\*</sup> Xtreme**  
**Cold and Cough**  
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 30 mL dose cup)**

Active ingredients	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine Succinate 12.5 mg	Antihistamine

**Uses** temporarily relieves cold/flu symptoms: • sore throat • headache • minor aches and pain • fever • runny nose and sneezing • cough due to minor throat and bronchial irritation

**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take • more than 4,000 mg of acetaminophen ▶

**Fast relief of:**  
SNEEZING & RUNNY NOSE  
FEVER  
ACHES & PAINS  
COUGH  
SORE THROAT

**Cherry Flavor Night Time Xtreme**  
**Multi-Symptom Cold/Flu Relief**  
**Cold and Cough**  
• Acetaminophen - Pain Reliever/Fever Reducer  
• Dextromethorphan HBr - Cough Suppressant  
• Doxylamine succinate - Antihistamine

6 FL OZ (177 mL)

**XL-3<sup>\*</sup> Xtreme**  
**Cold and Cough**

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**XL-3<sup>\*</sup> Xtreme**  
**Cold and Cough**

**Drug Facts (continued)**  
in 24 hours • with other drugs containing acetaminophen • 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, persists for more than two 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 ▶

**Drug Facts (continued)**  
(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. • to make a child sleepy.  
**Ask a doctor before use if you have** • a sodium restricted diet • liver disease • glaucoma • cough that occurs with too much phlegm (mucus) • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema • trouble urinating due to enlarged prostate gland.

**Drug Facts (continued)**  
**Ask a doctor or pharmacist before use** • if you are taking sedatives or tranquilizers • if you are taking the blood thinning drug warfarin.  
**When using this product** • do not use more than directed • avoid alcoholic drinks • excitability may occur, especially in children • marked drowsiness may occur • be careful when driving a motor vehicle or operating machinery • alcohol, sedatives and tranquilizers may increase drowsiness.  
**Stop use and ask a doctor if** • redness or swelling is present • symptoms do not get better within 7 days or are accompanied by a fever • fever gets worse or lasts more than 3 days • new symptoms occur • cough lasts more than 7 days, comes back, or occurs with fever, 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. ▶

**Drug Facts (continued)**  
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 recommended—see Overdose warning  
• Use dose cup or tablespoon (TBS) • do not exceed 4 doses per 24 hours  
• if taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours.

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

**Other information** • each 30 mL dose cup contains: sodium 45 mg  
• store at 20°–25 °C (68°–77 °F).

**Inactive ingredients** citric acid, FD & C Blue No.1, FD & C Red No.40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose.

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

**XL-3<sup>\*</sup> Xtreme**  
**Cherry Flavor**  
**Night Time**

**Multi-Symptom Cold/Flu relief**

**Cold and Cough**

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

**Fast Relief of:**

**SNEEZING & RUNNY NOSE**

**FEVER  
ACHES & PAINS  
COUGH  
SORE THROAT**

**6 FL OZ (177 mL)**

## XL-3\*

**Cherry Flavor  
Night Time Xtreme**

*Multi-Symptom Cold/Flu Relief*

### Cold and Cough

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

**Fast relief of:**

- ✓ SNEEZING & RUNNY NOSE
- ✓ FEVER
- ✓ ACHES & PAINS
- ✓ COUGH
- ✓ SORE THROAT

12 FL OZ (354 mL)

## XL-3\*

**Cherry Flavor  
Night Time Xtreme**

*Multi-Symptom Cold/Flu Relief*

### Cold and Cough

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

**Fast relief of:**

- ✓ SNEEZING & RUNNY NOSE
- ✓ FEVER
- ✓ ACHES & PAINS
- ✓ COUGH
- ✓ SORE THROAT

12 FL OZ (354 mL)

### XL-3\* Xtreme

*Cold and Cough*

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

Drug Facts	
<b>Active ingredients</b> (In each 30 mL dose cup)	<b>Purpose</b>
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine Succinate 12.5 mg	Antihistamine
<b>Uses</b> temporarily relieves cold/flu symptoms • sore throat • headache • minor aches and pain • fever • runny nose and sneezing • cough due to minor throat and bronchial irritation	

DRUG FACTS CONTINUED ON BACK

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## XL-3\* Xtreme

### Cold and Cough

#### Drug Facts (continued)

##### 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.

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

**Sore throat warning:** If sore throat is severe, persists for more than two 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 medication to 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. • to make a child sleepy.

##### Ask a doctor before use if you have

• a sodium restricted diet • liver disease • glaucoma • cough that occurs with low or high pH (legm) (mucus) • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema • trouble urinating due to enlarged prostate gland.

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

#### Drug Facts (continued)

**When using this product** • do not use more than directed • avoid alcoholic drinks • excitability may occur, especially in children • marked drowsiness may occur • be careful when driving a motor vehicle or operating machinery • alcohol, sedatives and tranquilizers may increase drowsiness.

**Stop use and ask a doctor if** • redness or swelling is present

• symptoms do not get better within 7 days or are accompanied by a fever • fever gets worse or lasts more than 3 days • new symptoms occur • cough lasts more than 7 days, comes back, or occurs with fever, 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 recommended • see Overdose warning

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

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

**Other information** • each 30 mL dose cup contains sodium 45 mg • store at 20°-25° (68°-77° F).

**Inactive ingredients** citric acid, FD & C Blue No. 1, FD & C Red No. 40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose.

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## XL-3<sup>®</sup> Xtreme

### Cold and Cough

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

**Active ingredients (in each 30 mL dose cup)**

Acetaminophen 650 mg ..... Pain reliever/fever reducer  
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**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take • more than 4,000 mg of acetaminophen ▶

DRUG FACTS CONTINUED ON BACK

# XL-3<sup>®</sup>

Cherry Flavor

## Night Time Xtreme

Multi-Symptom Cold/Flu Relief

### Cold and Cough

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

**Fast relief of:**

— SNEEZING & RUNNY NOSE

— FEVER

— ACHEs & PAINs

— COUGH

— SORE THROAT

6 FL OZ (177 mL)

## XL-3<sup>®</sup> Xtreme

### Cold and Cough

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## XL-3<sup>®</sup> Xtreme

### Cold and Cough

**Drug Facts (continued)**

in 24 hours • with other drugs containing acetaminophen • 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, persists for more than two 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 ▶

**Drug Facts (continued)**

(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. • to make a child sleepy.

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**Drug Facts (continued)**

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**Stop use and ask a doctor if** • redness or swelling is present • symptoms do not get better within 7 days or are accompanied by a fever • fever gets worse or lasts more than 3 days • new symptoms occur • cough lasts more than 7 days, comes back, or occurs with fever, 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. ▶

**Drug Facts (continued)**

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 recommended—see Overdose warning  
• Use dose cup or tablespoon (TBSP) • do not exceed 4 doses per 24 hours  
• if taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours.

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

**Other information** • each 30 mL dose cup contains: sodium 45 mg  
• store at 20°–25 °C (68°–77 °F).

**Inactive ingredients** citric acid, FD & C Blue No.1, FD & C Red No.40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose.

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

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<b>XL-3 XTREME</b>			
acetaminophen, dextromethorphan hbr, doxylamine succinate liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76281-305
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Acetaminophen (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	Acetaminophen	Acetaminophen	650 mg in 30 mL

<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-305-28	354 mL in 1 BOTTLE; 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 XTREME

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76281-307
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Acetaminophen</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	Acetaminophen	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE -	DOXYLAMINE SUCCINATE	12.5 mg

UNII:95QB77JKPL) DOXYLAMINE SUCCINATE in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-307-25	177 mL in 1 BOTTLE; 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(76281-305, 76281-307)

Revised: 12/2023

AptaPharma Inc.