**XL3 XTRA- acetaminophen chloepheniramine maleate dextromethorphan phenylepherine hydrochloride capsule liquid filled capsule, liquid filled**
**Teresa Cecena DBA Genesis**

*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.*

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DRUG FACTS

*Active Ingredient in each capsule*

Acetaminophen 250mg

Phenylepherine Hydrochloride 5mg

Chlorpheniramide Maleate 2mg

Dextromethorphan Hydrobromide 10mg

PURPOSE

Analgesic

Decongestant

Antihistamine

Antitussive

*USES*

Temporaruly relieves the symptoms due to common cold and allergies: Cough, nasal congestion, runny nose, sneezing, watery eyes, fever, aches and pains.

*WARNINGS*

DO NOT USE More than recommended dosage for pain more than 7 days for fever more than 3 days for children under 12 age with any other product containing acetaminophen.

***Alcohol Warning:***If you consume 3 or more alcoholic drinks every day, ask your doctor if you should take acetaminophen or other pain relivers fever reducers. Acetaminophen may casuse liver damage

**Ask a doctor befor** use you have

- Glaucoma, breathing problems such as emphysema or chronic bronchitis, heart disease, diabetes, thyroid disease.
- difficulty in urination due to enlagement of the prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

Do not take this product for persistent or chronic cough such as occur with smoking, asthma or emphysema, or if cough is accompanied by excessive phlegm (mucis) unless directed by doctor

Stop taking this product and ask a doctor if yoi have pain, fever or sympoms that persist or get worse ,

new symptoms occur

redness or swelling these may be be signs of a serious condition

When using this product

- you may get drowsy avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitabiloty may occur, especially in children

if nervousness, dizziness or spleeplessness occur discontinue use and consult a doctor

If symptoms do not improve within 7 days, or are accompanied by fever, consult a doctor

if you are pregnant or breast feeding, ask a health professional before use

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, get medical help or contac a poison control center immediately. Prompt medical attention is critical for adults as well as children ever if you do not notice any sings or symptoms .

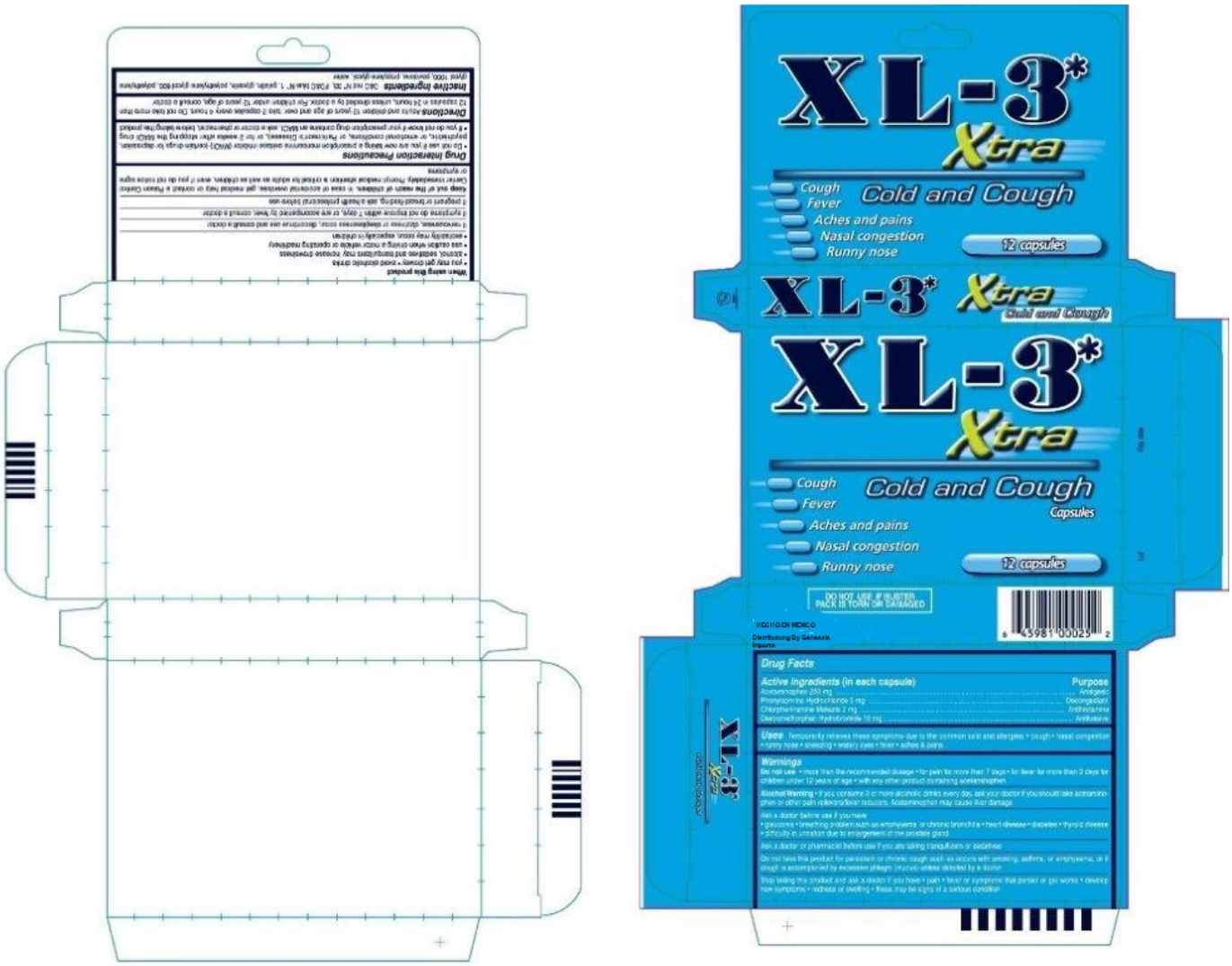
Drug unteraction precautions

do not use if you are taking a prescription monoamine oxidase ihibitor (MAOI) (certain drug for depression, psychoatric 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.

DIRECTIONS

Adults and children 12 years of age and older; take 2 capsules every 4 hours. Do not take more than 12 capsules in 24 hours, unless directed by doctor. For children under 12 years of age consult a doctor

DC red No. 33, FDC Blue No.1, gelatin, glycerin, polyethylene glycol 600, polyethylene glycol 1000, povidone, polyethylene glycol, water.

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# XL3 XTRA

acetaminophen chloepheniramine maleate dextromethorphan phenylepherine hydrochloride capsule liquid filled

capsule, liquid filled

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69772-440 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 1 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg in 1 mg |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 250 mg in 1 mg |
| **CHLORPHENIRAMINE MALEATE** (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 2 mg in 1 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) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | blue | **Score** | score with uneven pieces |
| **Shape** | CAPSULE (SOFT LIQUID FILLED CAPSULE) | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | Xtra |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:69772-440-01 | 20 mg in 1 BLISTER PACK; Type 0: Not a Combination Product | 09/02/2015 | |

| | | | | |
|---|---|---|---|---|
| **2** | NDC:69772-440-02 | 12 mg in 1 BLISTER PACK; Type 0: Not a Combination Product | 09/02/2015 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 08/07/2015 | |

## Labeler - Teresa Cecena DBA Genesis (078760958)

## Registrant - Teresa Cecena (078760958)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| TERESA CECENA | | 078760958 | relabel(69772-440) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Selder SA DE CV | | 824413629 | manufacture(69772-440) |

Revised: 8/2015 Teresa Cecena DBA Genesis