

NDC 52747-0420-70



Rx only

# norel<sup>®</sup> SR

Antihistamine, Analgesic, Decongestant

Each extended release tablet for oral administration contains:

- Acetaminophen . . . . . 325 mg
- Chlorpheniramine Maleate . . . . . 8 mg
- Phenylephrine HCl . . . . . 40 mg
- Phenyltoloxamine Citrate . . . . . 50 mg

### INDICATIONS AND USAGE

NOREL<sup>®</sup> SR is indicated for the temporary relief of allergy induced nasal congestion, runny nose, sneezing, headache and associated pain caused from inhalation of airborne antigens and other irritants. Consult package insert for full prescription information.

### DOSAGE AND ADMINISTRATION

Adults and children over 12 years of age:

1 tablet every 12 hours, not to exceed 2 tablets in 24 hours. Children under 12 years of age: take as directed by physician or other healthcare provider.

Tablets may be broken in half for ease of administration without affecting the release of the medication, but should not be chewed or crushed prior to swallowing. Do not exceed recommended dosage.

NDC 52747-0420-70



Rx only

# norel<sup>®</sup> SR

Antihistamine, Analgesic, Decongestant

## norel<sup>®</sup> SR

Antihistamine, Analgesic, Decongestant

### Pharmacy Information

Wholesaler	Available	Order Number
Amerisource Bergen	Yes	002636
Cardinal Health	Yes	3609450
H.D. Smith Wholesale Drug	Yes	1659085
McKesson Drug Company	Yes	1258292
Morris & Dickson	Yes	557066
N.C. Mutual Wholesale Drug	Yes	453530
Smith Drug Company	Yes	391714



You should call your healthcare provider for medical advice about adverse events. To report a serious adverse event, contact US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036. Marketed by US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036.

Rev. 10/2010



**US Pharmaceutical Corporation**  
Products designed with the patient in mind.™

NDC 52747-0420-70



Rx only

# norel<sup>®</sup> SR

Antihistamine, Analgesic, Decongestant

## Fast and Extended Relief of:



Nasal Congestion



Runny Nose



Sneezing



Sinus Headaches

Patients 12 years of age and older:

# 1 Tablet B.I.D.

This product information is intended for physicians and is the entire product information. NO OTHER INFORMATION, WHETHER ORAL OR IN WRITING, SHOULD BE RELIED UPON!

NDC 52747-420-70

**NOREL® SR**

Antihistamine, Analgesic and Decongestant

Rx only

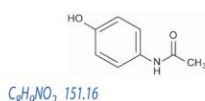
#### DESCRIPTION

Each extended release tablet for oral administration contains:

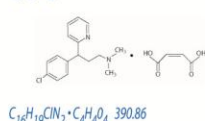
Acetaminophen	325 mg
Chlorpheniramine Maleate	8 mg
Phenylephrine HCl	40 mg
Phenyltoloxamine Citrate	50 mg

In a specially prepared base, to provide a prolonged therapeutic effect.

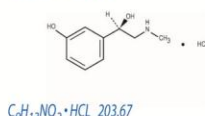
Acetaminophen, 4-Hydroxyacetanilide, is a non-opiate, non-salicylate. It has the following structural formula:



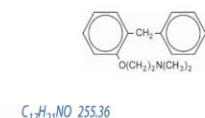
Chlorpheniramine maleate, 2-Pyridinepropanamine, g-(4-chlorophenyl)-N,N-dimethyl-, (Z)-2-butenedioate (1:1), is an antihistamine. It has the following structural formula:



Phenylephrine hydrochloride, Benzenemethanol,3-hydroxy-α-[(methylamino)z-methyl]-, hydrochloride (R), is a sympathomimetic amine. It has the following structural formula:



Phenyltoloxamine Citrate, N,N-dimethyl-2-(α-phenyl-o-tolyl)oxyethylamine dihydrogen citrate, is an adjuvant to acetaminophen. It has the following structural formula:



Also includes the following as inactive ingredients: calcium phosphate, magnesium stearate, methylcellulose, povidone, silicified microcrystalline cellulose, D&C Yellow #10, FD&C Yellow #6.

#### CLINICAL PHARMACOLOGY

The mechanism of analgesic action of acetaminophen has not been fully determined. Acetaminophen may act by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, through peripheral action, by blocking pain-impulse generation. The peripheral action may also be due to inhibition of the synthesis of prostaglandins or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

Chlorpheniramine maleate is an alkylamine-type antihistamine. This group of antihistamines is among the most active histamine antagonists and are generally effective in relatively low doses.

Phenylephrine hydrochloride is primarily a direct-acting sympathomimetic amine. Sympathomimetic amines act on alpha-adrenergic receptors in the mucosa of the respiratory tract to produce vasoconstriction, which temporarily reduces the swelling associated with inflammation of the mucous membranes lining the nasal passages.

Phenyltoloxamine Citrate is an ethanol amine-type compound used as an adjuvant with acetaminophen to mediate the release of bradykinin and prostaglandin, two agents involved in the cause of inflammatory pain.

#### INDICATIONS AND USAGE

NOREL® SR is indicated for the temporary relief of allergy induced nasal congestion, runny nose, sneezing, headache and associated pain caused from inhalation of airborne antigens and other irritants.

#### CONTRAINDICATIONS

NOREL® SR should not be administered to patients who have previously exhibited hypersensitivity to any of the ingredients. Risk-benefit should be considered when any of the following medical problem exist: alcoholism, asthma, bladder-neck obstruction, urinary retention, cardiovascular disease, diabetes mellitus, glaucoma, hepatic function impair, hypertension, hyperthyroidism, prostatic hypertrophy, psychosis or other psychiatric disorders, renal function impairment, viral hepatitis.

#### WARNINGS

If pain or fever persists, if new symptoms occur, or if redness or swelling is present, consult your physician immediately because these could be signs of a serious condition. Do not give this product to children under 12 years of age unless directed by a physician. Caution should be exercised when used in patients with prostatic hypertrophy, urinary retention, bladder neck obstruction, increased ocular pressure, and asthma.

#### PRECAUTIONS

Information for Patients: Patient consultation should include the following information regarding the proper use of NOREL® SR:

- Do not exceed recommend dosage.
- May be taken with food, water, or milk to lessen gastric irritation.
- Do not drive or operate heavy machinery if drowsiness or dizziness occurs.
- Concomitant use of alcohol and other central nervous system depressants (hypnotics, sedatives, tranquilizers and anti-anxiety drugs) while taking NOREL® SR may have an additive effect on drowsiness.
- If a dose is missed, the medication should be taken as soon as possible unless it is almost time for the next dose. Doses should not be doubled.
- Tablet may be broken in half for ease of swallowing without affecting release of the medication, do not chew or crush before swallowing.

Laboratory Tests: In patients with severe hepatic or renal disease, effects of therapy should be monitored with serial liver and/or renal function tests.

Drug Interactions: Combinations containing any of the following medications, depending on the amount present, may interact with NOREL® SR: CNS depressants/stimulants, antihistamines, anticholinergics, anesthetics, digitalis glycosides, tricyclic antidepressants, diuretics, beta-adrenergic blocking agents, doxapram, MAOI's, ototoxic medications, rauwolfia alkaloids, hepatic enzyme inducers, hepatotoxic medications, anticoagulants, NSAID's, aspirin or other salicylates, zidovudine. Drug/Laboratory Tests Interactions: Acetaminophen may produce false positive tests results for urinary 5-hydroxyindoleacetic acid. Blood glucose determinations may be falsely decreased by acetaminophen when measured by the glucose oxidase / peroxidase method. Antihistamines may inhibit the cutaneous histamine response of skin tests using allergen extracts, thus producing false-negative results. The sedative effects of chlorpheniramine and phenyltoloxamine are additive to the CNS depressant effects of alcohol, hypnotics, sedatives and tranquilizers.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No adequate studies have been conducted in animals or humans to determine whether NOREL® SR has a potential for carcinogenesis, mutagenesis, or impairment of fertility.

Pregnancy: Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. NOREL® SR should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.

Nursing Mothers: Small amounts acetaminophen, antihistamines, and sympathomimetics are excreted in breast milk. Due to the potential for serious adverse reactions in nursing infants from NOREL® SR, the healthcare provider must decide whether to discontinue the drug during nursing, taking into account the health benefits to the mother.

Pediatric Use: Pediatric patients may be more sensitive to the effects of NOREL® SR. Very young children may be more susceptible to the effects, especially the vasopressor effects, of sympathomimetics. In older children taking antihistamines, a paradoxical reaction characterized by hyperexcitability may occur.

Geriatric Use: Geriatric patients may be more sensitive to the effects of NOREL® SR. Confusion, dizziness, sedation, hallucination, hypotension, hyperexcitability, seizures, CNS depression, vasopressor and anticholinergic side effects may be more likely to occur in geriatric patients.

#### ADVERSE REACTIONS

The following adverse effects have been selected on the basis of their potential clinical significance (not necessarily inclusive): allergic reactions, anemia, blood dyscrasias (sore throat and fever, unusual bleeding or bruising, unusual tiredness or weakness), psychotic episodes (mood or mental changes) - usually associated with previous history of psychiatric illness, tightness in chest.

#### OVERDOSAGE

Signs and symptoms: anticholinergic effects (clumsiness or unsteadiness; severe dryness of mouth, nose, or throat; flushing or redness of face; shortness of breath or troubled breathing), CNS stimulation (hallucinations, seizures, trouble in sleeping), drowsiness (severe), hypertension, diarrhea, increased sweating, loss of appetite, nausea, vomiting, stomach cramps or pain. Hepatotoxicity - signs and symptoms may occur 2 to 4 days after ingestion (pain or tenderness in the upper abdominal area, swelling of abdominal area).

Recommended Treatment: Recommended treatment of overdose consists of the following: Emptying the stomach via induction of emesis or gastric lavage.

- For excessive hypertensive effect, an alpha-adrenergic blocker, such as phentolamine, may be administered.
- Administering activated charcoal. However, activated charcoal may interfere with absorption of oral acetylcysteine.
- Acetylcysteine is recommended as soon as possible after ingestion of an overdose, without waiting for results of plasma acetaminophen determinations or other lab tests. Acetylcysteine is most effective if treatment is started within 10 to 12 hours after ingestion of the overdose.
- Instituting hemodialysis or hemoperfusion to remove acetaminophen from the circulation may be beneficial if acetylcysteine cannot be administered within 24 hours after overdose.
- Monitoring renal and cardiac function and administering appropriate therapy as required
- Instituting supportive therapy, including maintaining fluid and electrolyte balance, correcting hypoglycemia and administering vitamin K<sub>1</sub> and fresh frozen plasma or clotting factor concentrate.

Serum acetaminophen levels should be obtained at least 4 hours following overdose. Determinations performed prior to this time are not reliable for assessing potential hepatotoxicity.

Hepatic enzymes should be obtained initially, and repeated at 24-hour intervals for at least 96 hours post ingestion.

#### DOSAGE AND ADMINISTRATION

Adults and children over 12 years of age: 1 tablet every 12 hours, not to exceed 2 tablets in 24 hours. Children under 12 years of age: take as directed by physician or other healthcare provider. Tablets may be broken in half for ease of administration without affecting the release of the medication, but should not be chewed or crushed prior to swallowing. Do not exceed recommended dosage.

#### HOW SUPPLIED

Bottles of 100 (NDC 52747-420-70) yellow & white bi-layer, triangle-shaped tablets debossed "04" bisected "20" on one side, "US" on the opposite.

#### CAUTION: Rx only

Store at controlled room temperature 20°- 25°C (68°- 77°F). Dispense in tight, light-resistant containers as defined in USP/NF with a child-resistant closure.

KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

You should call your healthcare provider for medical advice about adverse events. To report a serious adverse event, contact US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036.

Marketed by US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036. The white and yellow triangular shape and name of NOREL® SR tablets are registered trademarks of US Pharmaceutical Corporation, Decatur, GA 30035

Rev.10/2010

visit [norelSR.com](http://norelSR.com) for:



An up-to-date copy of this Product Literature



Comments or Questions



Product Feedback