Norel SR Tablets: Package Insert / Prescribing Info

Package insert / product label
Generic name: acetaminophen, chlorpheniramine maleate, phenylephrine hydrochloride and phenyltoloxamine citrate
Dosage form: tablet, extended release
Drug class: Upper respiratory combinations

Medically reviewed by Drugs.com. Last updated on Mar 25, 2025.

On This Page

DESCRIPTION

Each extended release tablet for oral administra- tion contains: Acetaminophen..... 325 mg Chlorpheniramine Maleate ..... 8 mg Phenylephrine HCl..... 40 mg Phenyltoloxamine Citrate ..... 50 mg

CLINICAL PHARMACOLOGY

The mechanism of analgesic action of acetaminophen has not been fully deter- mined. Acetaminophen may act by inhibiting pro-staglandin 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 pro-staglandins 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 anti-histamine. 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 pro-staglandin, 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 problems exist: alcoholism, asthma, bladder-neck obstruction, urinary reten- tion, cardiovascular disease, diabetes mellitus, glaucoma, hepatic function impairment, 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 pre- sent, 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 pro-static 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 recommended dosage.
• May be taken with food, water, or milk to lessen gastric irritation.
• Do not drive or operate heavy machinery if drowsi- ness or dizziness occurs.
• Concomitant use of alcohol and other central nervous system depressants (hypnotics, sedatives, tranquilizers and anti-anxiety drugs) while tak ing 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.
• Swallow extended-release tablets whole; do not crush or chew tablets prior to swallowing.

Laboratory Tests: In patients with severe hepatic or renal disease, effects of therapy should be moni- tored 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, anti cholinergics, anesthetics, digitalis glyco-sides, tricyclic antidepres- sants, diuretics, beta-adrenergic blocking agents, doxapram, MAOI's, ototoxic medications, rauwolfia alka- loids, hepatic enzyme inducers, hepatoxic medications, anticoagulants, NSAID's, aspirin or other salicylates, zidovudine.

Drug/Laboratory Tests Interactions: Acetamin- ophen 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, seda- tives and tranquilizers.
Carcinogenesis, Mutagenesis, Impairment of Fertility: No adequate studies have been conduct- ed in animals or humans to determine whether NOREL® SR has a potential for car- cinogenesis, 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 of acetaminophen, antihistamines, and sympa- thomimetics are excreted in breast milk. Due to the potential for serious adverse reactions in nurs- ing infants from NOREL® SR, the healthcare provider must

decide whether to dis- continue the drug during nursing, taking into account the health benefits to the mother.

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

Geriatric Use: Geriatric patients may be more sensi- tive to the effects of NOREL® SR. Confusion, dizziness, sedation, halluci- nation, hypotension, hyper-exitability, 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: anti- cholinergic effects (clumsi- ness 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. Hepato toxicity signs and symptoms may occur 2 to 4 days after ingestion (pain or tenderness in the upper abdominal area, swelling of abdom- inal area).

Recommended Treatment: Recommended treatment of overdose consists of the following:

• Emptying the stomach via induction of emesis or gastric lavage.

• For excessive hyperten- sive effect, an alpha-adrenergic blocker, such as phentolamine, may be administered.

• Administering activated charcoal. However, activated charcoal may inter- fere with absorption of oral acetylcysteine.

• Acetylcysteine is recommended as soon as pos- sible after ingestion of an overdose, without wait- ing 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 acetycysteine cannot be adminis- tered within 24 hours after overdose.

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

• 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 K1 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 hepatoxicity.

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. Swallow extended-release tablets whole; do not crush or chew tablets prior to swallowing. Do not exceed recommended dosage.

HOW SUPPLIED Bottles of 100 (NDC 52747- 420-70)

Enter section text here

NDC 52747-420-70

Norel® 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

100 Tablets

℞ ONLY

Indications: This product is an antihistaminic nasal decongestant also used as an analgesic to treat pain and headache.

Directions: As directed by a physician.
Consult package insert for full prescription information.

Rx only.
Rev. 02/2006

400218

Marketed by:
US Pharmaceutical Corporation
Decatur, GA 30035
www.uspco.com

How Supplied: Bottles of 100 yellow & white bi-layer, triangle-shaped tablets debossed "04" bisected "20" on one side, "US" on the opposite.

Keep this and any other drugs out of the reach of children.

Dispense in a tight, light-resistant container as defined in the USP/NF, with a child- resistant closure. Store at 20°- 25°C (68°- 77°F), see USP Controlled Room Temperature.

MADE IN U.S.A.

NOREL SR

antihistamine, analgesic, decongestant tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52747-420
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	8 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	40 mg
Phenyltoloxamine Citrate (UNII: 8UE48MJH8M) (Phenyltoloxamine - UNII:K65LB6598J)	Phenyltoloxamine Citrate	50 mg

Inactive Ingredients

Ingredient Name	Strength
Calcium Phosphate (UNII: 97Z1WI3NDX)	
Magnesium Stearate (UNII: 70097M6I30)	
Povidone (UNII: FZ989GH94E)	

Product Characteristics

Color	yellow (yellow & white)	**Score**	no score
Shape	TRIANGLE	**Size**	20mm
Flavor		**Imprint Code**	Norel;SR
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52747-420-70	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2008	03/31/2013

Labeler - US Pharmaceutical Corporation (048318224)

Registrant - US Pharmaceutical Corporation (048318224)

More about Norel SR (acetaminophen / chlorpheniramine / phenylephrine / phenyltoloxamine)

- Check interactions
- Compare alternatives
- Reviews (6)
- Drug images
- Dosage information
- Drug class: upper respiratory combinations

Related treatment guides

- Nasal Congestion
- Cold Symptoms

Medical Disclaimer

DRUG STATUS

Availability
Discontinued

CSA Schedule*
N/A Not a controlled drug

User Reviews & Ratings

6 Reviews

Images

Norel SR acetaminophen 325 mg / chlorpheniramine 8 mg / phenylephrine 40 mg / phenyltoloxamine 50 mg (US 04 20)






Drugs.com provides accurate and independent information on more than 24,000 prescription drugs, over-the-counter medicines and natural products. This material is provided for educational purposes only and is not intended for medical advice, diagnosis or treatment. Data sources include Micromedex (updated 7 Apr 2025), Cerner Multum™ (updated 13 Apr 2025), ASHP (updated 10 Apr 2025) and others.