NADOXOL Inj. (Ambroxol HCl15mg)

■ **COMPOSITION**

Each ampoule(2mL) contains 15mg of Ambroxol hydrochloride.

■ **INDICATIONS**

1) Acute.chronic respiratory diseases caused by respiratory mucosa-secretion disturbance, such as chronic bronchitis, asthmatic bronchitis and bronchial asthma,
2) Difficult breathing syndrome in premature infants and neonates.
3) In pre- and post-operation, Prevention and treatment of pulmonary complication

■ **DOSAGE & ADMINISTRATION**

Adults : 1 ampoule at once is intravenously, intramuscularly or subcutaneously administered 2 to 3 times a day. In severe symptoms, this dose may be increased to 2 ampoules at once.

Children : The following dosage is intravenously or intramuscularly administered (The recommended daily dosage is 1.2 - 1.6mg/kg as Ambroxol HCl) ;

Age	Daily dosage
Under 2 years	½ ampoule, twice a day
2 to 5 years	½ ampoule, 3 times a day
Over 5 years	1 ampoule, 2-3 times a day

For the treatment of dyspnea in premature infants and neonates, 10mg per kg bodyweight as ambroxol HCl is slowly IV-injected in 4 divided doses. The dosage can be increased until 20mg/kg bodyweight when it is used alone.

■ **PRECAUTION**

1. CONTRAINDICATIONS
The patients with hypersensitivity to this drug
2. SHOULD BE ADMINISTERED CAUTIOUSLY TO THE FOLLOWING PATIENTS
The patients with severe renal disorder
3. ADVERSE REACTIONS
1) Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are rare but severe cutaneous adverse reactions (SCAR) related to Antitussives & Expectorants.
2) Gastrointestinal : rarely stomach upset, abdominal fullness, abdominal pain, diarrhea, constipation, nausea, vomiting, heartburn, anorexia, etc. may occur
3) Hypersensitivity : rarely rash, hives, erythema, itching, face swelling, dyspnea, temperature elevation with chills, etc. may occur. It is reported that rarely severe acute anaphylaxic reaction independent with ambroxol occurred. in such a case, discontinues the therapy
4) Respiratory : suppurative rhinitis with leukocytosis may occur.
5) Other : rarely oral paralysis and paralysis of arm may occur.
4. DRUG INTERACTION
The concomitant administration with antibiotics such as erythromycin, cephalexin, oxytetracyclin, amoxicillin, cefuroxim, doxycyclin increase the antibiotic action on lung.
5. USE IN PREGNANCY AND NURSING MOTHER
As the safety during pregnancy has not yet been estabilished, this drug should be used during pregnancy or suspected pregnancy only if the potential benefits overweigh the possible risks. (especially should not be administered during the first trimester of pregnancy)
6. USE IN THE ELDERLY
Should be administered cautiously to the elderly
7. GENERAL PRECAUTIOUS
1) Headache, leg pain, extreme fatigue may occur, so inject slowly
2) When NADOXOL is subcutaneously or intramuscularly adminitered, be careful to avoid injecting on the vessel, nerve and the same site repeatedly. When NADOXOL is intravenously administered, should be injected slowly.
3) As precipitation of NADOXOL may occur, this drug should not be mixed with other injectable solutions of more than pH 6.3.

■ **STORAGE** : Light-resistant, hermetic container

■ **USE TERM** : 3 years

■ **PACKS** : Boxes of 50 ampoules

※ Medicine : Keep out of reach of children.

This drug is manufactured in accordance with Korea Good Manufacturing Practice (KGMP)as recommended by WHO.