

Scheduling status

S1

Proprietary name (and dosage form)

NUELIN 125 mg Tablets

Composition

Each Nuelin tablet contains 125 mg theophylline BP.

Pharmacological classification

A10.2 Bronchodilators

Pharmacological action

At the cellular level, the bronchodilatory effect of theophylline is thought to be due to an inhibition of the enzyme nucleotide phosphodiesterase. This enzyme is responsible for the destruction of cyclic 3,5-AMP. The effects of theophylline on bronchial smooth muscle are similar to those produced by bronchodilatory sympathomimetic amines. This similarity is probably related to their common ability to increase the cyclic 3,5-AMP concentration in the tissues. This may account for the fact that there is synergism between sympathomimetic amines and theophylline.

Indications

Nuelin tablets are indicated for the treatment of bronchial asthma and other conditions accompanied by bronchospasm.

Contra-indications

There are no known contra-indications to theophylline therapy, but other theophylline therapy should not be administered concurrently with Nuelin tablets. Theophylline may also reduce the therapeutic effect of lithium.

Warnings

None

Dosage and directions for use

1. Adults and children over 12 years:

For severe attack: 3 tablets every six hours

Maintenance dose: 3 tablets initially, then 1 tablet every six hours.

2. Children under 12 years:

20 – 35 kg (7 – 12 years):

Severe attack: 1 to 2 tablets every six hours

Maintenance dose: ½ to 1 tablet every six hours

10 – 20 kg (2 – 6 years):

Severe attack: ½ to 1 tablets every six hours

Maintenance dose: up to half a tablet every six hours

Not recommended for infants under 10 kg.

Side effects and special precautions

Side-effects associated with the use of xanthine derivatives include the following: insomnia, headache, nausea, vomiting, diarrhoea, diuresis, tremor, malaise, excitation, anorexia, dizziness, gastralgia, tachycardia and palpitations, reduced exercising ability, excessive sweating and a metallic taste in the mouth.

The gastric irritation commonly associated with xanthine derivatives may occur.

The dosage must be reduced in the elderly and in patients with cardiac failure and impaired hepatic function.

The maintenance dose of 0.6 – 0.9 mg per kg per day will achieve therapeutic blood levels in most patients. However, individual biotransformation may vary. Where possible, it is advisable to monitor theophylline therapy with serum theophylline determinations.

Known symptoms of overdose and particulars of its treatment

Symptoms: See side effects. Hypotension and convulsions may occur.

Treatment: Gastric lavage and general supportive measures are recommended.

Identification

White, round, biconvex tablets, imprinted 'Riker 125' on one side and 'N/L' on the other.

Presentation

Bottles of 100 tablets.

Storage instructions

Containers should be stored below 30 °C, tightly closed.

KEEP OUT OF REACH OF CHILDREN

Registration number

H/10.2/296

Name and business address of applicant

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