FLUIMUCIL®

Zambon

Patient's leaflet

FLUIMUCIL®

Granulate/Effervescent tablets/Syrup read for the use
Mucolytic.
Composition
Active ingredient :N- acetylcysteine
Granulate as 1400,200 and 600mg N-acetylcysteine sachets
Excipients: flavours , aspartame, sorbitol
Effervescent tablets , 200 and 600 mg N-acetylcysteine
Excipients : flavours, aspartame.
Syrup ready for the use :100mg N-acetylcysteine/5 ml
Excipients : flavours,saccharin , preservative agents :E 218, E211

Properties / Effects
Fluimucil contains the active ingredient N-acetylcysteine , a cysteine derivative with a reactive free thiol group , possessing both mucolytic and antioxidant properties.
The mucolytic action of N-acetylcysteine is based on the direct N-acetylcysteine and indir glutathione inactivating action on electrophili and oxidant compounds.
Through cysteine , N-acetylcysteine makes available an essential glutathione synthesis precursor, with a consequent increase in glutathione endogenous supplies.
Exogenous and endogenous oxidants, that can be neutralized by N-acetylcysteine and glutathione, have in fact a role in the pathogenesis of inflammatory respiratory airways disease
Pharmacokinetics
Absorption
N-acetylcystein absorption after oral administration is prompt and complete.
Distribution :
N-acetylcysteine is principally spread within t aqueous environment of the extracellular spac It can be localized mainly at level of the liver kidneys , lungs and bronchial mucus.
Metabolism
The metabolization process starts soon after tl product administration : N-acetylcysteine is deacetylated at level of the intestinal wall and upon its first liver passage to L-cysteine and then metabolized to inactive bonds.
Elimination
About 30 % of the administered dose is eliminated directly by renal excretion .

Indications /Possibilities of use
All respiratory airways diseases , causing formation of a dense secretion that cannot be can only partially be expectorated , such as acute and chronic bronchitis , laryngitis , sinusitis , tracheitis , influenza , bronchial asthma and (as complementary treatment) mucoviscidosis .

Posology /Instruction for use
Usual dosage for acute diseases
Children from1 to 2 years of age : 2.5 ml syru ready for the use 3 times /day
Children from 2 to 12 years of age :300-400 r daily , one 100 mg sachet or 5 ml syrup read for the use 3 times /day or one 200 mg effervescent tablet twice a day.
Children beyond 12 years of age and adults : 600 mg /day , divided into one (one 600 mg effervescent tablet or sachet, preferably in the evening) or more administrations (e.g. 200 r or 10 ml syrup ready for the use 3 times/day)
Special dosage instructions
Children :In children with age ranging betwe 1 and 2 years , Fluimucil must be administere only under medical prescription, whilst for suckling and children below 1 year of age , a steady medical surveillance within a hospital environment is required
Long-term treatment : 400 mg /day , divide into 2 administrations ; the maximum treatme duration ranges between 3 and 6 months.
Should the excessive mucus production and tl relevant cough not disappear after a 2 –week treatment , then the diagnosis is to be appropriately checked by the physician, who l to examine the possible cause of such persistence ,so as to exclude , for example, a maligne respiratory airways disease.
Mucoviscidosis : as above , but for children a from 6 years of age one 200 mg sachet or 10 r syrup ready for the use 3 times /day , or one 6 mg effervescent tablet or granulate sachet onc day .
Dissolve the content of one sachet or effervescent table into a glass of cold or warn water.
It is not suggested to dissolve Fluimucil concomitantly with other medicines.
The slight sulphur odor that could be perceive upon sachet or blister opening , evaporates rapidly, and has no influence of the preparatic efficacy.
Use restrictions
Contraindications
The product must not be administered in case of:
- Active peptic ulcer
- Ascertained hypersensitivity to N-acetylcysteine.

- Syrup ready for the use: children below 12 years of age (for children with mucoviscidosis: below 6 years of age)
- Concomitant use of an antitussive is medically not appropriate (see "Precautions"

Precautions

Special caution is required for patients with risk of gastrointestinal bleeding (e.g with lat peptic ulcer of esophagus varices) , since Nacetylcystein oral administration can induc vomiting.

Owing to the risk of bronchospasm, special caution is required for patients suffering forr bronchial asthma or with hyperreactive bronchial system.

In case of onset of hypersensitivity reactions bronchospasm , the product administration must be immediately discontinued , and appropriate therapeutic measures are to be avoided , as they suppress the cough reflex a the physiologic self-cleaning mechanism of respiratory airways , thus causing a mucus stasis with possible risk of bronchospasm an respiratory airways infections (see "Contraindications").

Subjects suffering from hypertension , for whom the salt use in precluded, must consid that each 200 and 600 mg acetylcysteine effervescent table contains about 140 mg sodium (corresponding to About 350 mg Na For these cases , it is suggested to use Fluimucil granulate or syrup ready for the us or other salt –free acetylcysteine preparation

Pregnancy /Lactation

Pregnancy category B.

FLuimucil must be administered only under strict medical control during the pregnancy period .

No studies concerning the passage of N-acetylcysteine into the mother's milk are available Therefore , by considering both the possible risks of adverse reactions in sucklin and the therapeutic benefits of lactation, all mothers under therapy with FLuimucil shoul discontinue lactation.

Adverse events

Sometimes mild gastrointestinal disturbance such as pyrosis , nausea , vomiting or diarrh and , in seldom cases urticaria , headache an fever are reported .In predisposed patients , hypersensitivity reactions affecting skin and respiratory organs may appear , The patient' breath could have an unpleasant odour , probably due to the division of sulphur hydrogen.

Interactions

Qwing to N-Acetylcysteine reactive thiol group , the effect of ampicillin , tetracycline macrolides, cephalosporins, aminoglycoside and amphotericin could be decreased in case direct N-acetylcysteine contact with these substances (aerosol solutions , perfusions , etc.)As for amoxicillin , it must be noted tha concomitant administration of N-Acetylcysteine and this antibiotic , it is suggested to space out the administration by least a 2- hour interval.

In case of concomitant administration of glyceryl nitrate , the relevant vasodilating a thombocyte aggregation inhibiting effect could be increased .

Concomitant antitussive administration : se Use restrictions"

Over dosage

No N- acetylcysteine overdosage was reported so far.

Special warnings

Storage

Fluimucil is to be stored away from light a humidity .Keep the product away from the reach of children.

The medicine must not be used beyond the expiry date printed on the product packagir ,which is indicated with the abbreviation "EXP"

Once opened , the syrup ready for the use c be stored for 15 days at room temperature (15-25˚C)

Incompatibilities

N-acetylcysteine is incompatible with most metals , and is inactivated by oxidizing substances

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