NAME:

BRONCHENOL _ SEDATIVE AND FLUIDIFYING

PHARMACOTHERAPY GROUP:

Cough sedatives and expectorants in combination, opium derivatives and expectorants.

ACTIVE INGREDIENTS:

100 ml of syrup contains active ingredients: dextromethorphan hydrobromide 0.15 g and guaifenesin 1.00 g; excipients with known effects: liquid sucrose 73.50 g, propyl para-hydroxybenzoate 0.025 g, methyl par-hydroxybenzoate 0.075 g, ethyl alcohol 5.00 g.

One tablet contains active ingredients: dextromethorphan hydrobromide 7.5 mg and guaifenesin 55 mg; excipients with known effects: sucrose 2080.92 mg, aspartame (E951) 23 mg.

For the full list of excipients, see section 6.1.

EXCIPIENTS:

Bronchenol Sedative and Fluidizing syrup, 100 ml of syrup contains: pine thrush essential oil; citric acid monohydrate; alcohol; glycerol; liquid sucrose; sweet orange essence; propyl para-hydroxybenzoate; methyl para-hydroxybenzoate; sodium saccharin; purified water.

Bronchenol Sedative and Fluidizing mint flavored tablets, a 2.3 g tablet of Bronchenol Sedative and Fluidifying mint flavor contains: pine-mugo essential oil; magnesium trisilicate; aspartame; magnesium stearate; sucrose; mint flavor.

INDICATIONS:

Symptomatic treatment of cough.

CONTRAINDICATIONS/ SIDE EFFECTS:

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Children under 6 years old.

Patients who are taking or have taken monoamine oxidase inhibitor (MAOI) antidepressants in the last two weeks (see section 4.5).

Patients with respiratory failure or at risk of developing respiratory failure (e.g. patients with chronic obstructive respiratory disease or pneumonia, patients with current asthma attack or asthma exacerbation).

DOSAGE:

The use of the medicinal product should be limited to the lowest effective dose and the shortest possible period (see section 4.4).

Syrup

Adults and adolescents over 12 years:
the recommended dose is 10 ml (corresponding to 2 teaspoons) 2 - 4 times a day, with a minimum interval between doses of 6 hours.

The maximum daily dose is 40 ml (corresponding to 8 teaspoons).

Do not exceed the maximum recommended daily dose.

Children from 6 to 12 years:
the recommended dose is 5 ml (corresponding to 1 teaspoon) 3 - 4 times a day, with a minimum interval between doses of 6 hours.

The maximum daily dose is 20 ml (corresponding to 4 teaspoons).

Do not exceed the maximum recommended daily dose.

1 ml of syrup contains: 1.5 mg of dextromethorphan hydrobromide and 1 mg of guaifenesin.

Pills

Adults and adolescents over 12 years old:
the recommended dose is 3-6 tablets per day to dissolve in the mouth, with a minimum interval between doses of 4 hours.

The maximum daily dose is 6 tablets.

Do not exceed the maximum recommended daily dose.

Children from 6 to 12 years old:
the recommended dose is 2-3 tablets per day to dissolve in the mouth, with a minimum interval between doses of 8 hours.

The maximum daily dose is 3 tablets.

Do not exceed the maximum recommended daily dose.

It is recommended to supervise the child while taking the pill.

Duration of treatment: the treatment should not be longer than 5 days.
In the absence of a therapeutic response, re-evaluate the situation.
Method of administration: oral use.

CONSERVATION:

Mint-flavored tablets: none
Syrup: do not store above 25 degrees C.

WARNINGS:

Sedative and Fluidizing Bronchenol should only be used after careful medical evaluation in case of: chronic or persistent cough, the causes of which requiring specific etiological treatment should be investigated; severe hepatic and renal insufficiency.

In the event that the cough persists, worsens or is accompanied by alt-a fever, rash or persistent headache, it is recommended to re-evaluate the clinical picture.

Dextromethorphan can be addictive.

Following prolonged use, patients may develop tolerance to the medicinal product, as well as mental and physical dependence (see section 4.8).

Cases of abuse and dependence of dextromethorphan have been reported.

Special attention is recommended with adolescents and young adults and children, as well as patients with a history of alcoholism, drug abuse or psychoactive substances.

Patients with a tendency to abuse or dependence should take Bronchenol Sedative and Fluidizing for short periods and be carefully monitored.

Alcohol intake during treatment is not recommended.

Dextromethorphan is metabolised by hepatic cytochrome P450 2D6 (see section 5.2).

The activity of this enzyme is genetically determined.

Approximately 10% of the population metabolises CYP2D6 slowly.

Excessive and/or prolonged effects of dextromethorphan may occur in slow metabolisers and patients with concomitant use of CYP2D6 inhibitors.

Therefore, caution should be exercised in patients who are CYP2D6 metabolisers or use CYP2D6 inhibitors (see section 4.5).

Risks arising from the concomitant use of sedative drugs such as benzodiazepines or related drugs: the concomitant use of Bronchenol Sedative and Fluidizer and sedative drugs such as benzodiazepines, or related drugs, may cause sedation, respiratory depression, like and death.

Because of these risks, concomitant prescription with sedative medicinal products should be limited to patients for whom alternative treatments are not possible.

If the decision is made to prescribe Bronchenol Sedative and Fluidizer with medicinal products with sedative action, the lowest effective dose should be used and the duration of treatment should be as short as possible (see also general dose recommendations in section 4.2).

Patients should be closely monitored for signs and symptoms of respiratory depression and sedation.

In this regard, it is strongly recommended to inform patients and who care after them (where applicable) so that they are aware of these symptoms (see section 4.5).

Serotonin syndrome: serotonin effects, including the development of a life-threatening serotonin syndrome, have been reported for dextromethorphan with concomitant administration of serotonin agents, such as selective serotonin reuptake inhibitors (SSRIs), drugs that alter serotonin metabolism (including monoamine oxidase inhibitors [MAOIs) and C YP2D6 inhibitors).

Serotonin syndrome can include changes in mental status, autonomic instability, neuromuscular abnormalities and/or gastrointestinal symptoms.

If serotonin syndrome is suspected, treatment with Sedative and Fluidizing Bronchenol should be discontinued (see sections 4.4 and 4.8).

Pediatric population: serious adverse events, including neurological disorders, may occur in children.

In this regard, it is strongly recommended to inform those who care after them (where applicable) so that they are aware of the possible symptoms of respiratory depression and sedation.

Information on excipients with known effects.

Bronchenol Sedative and Fluidizing syrup contains, liquid sucrose: contains 7.35 g of sucrose (sugar) for a dose of 10 ml.

To be taken into consideration in patients with diabetes mellitus.

Patients with rare problems of fructose intolerance, glucose-galactose malabsorption, or isomaltase insufficiency should not take this medicine; ethyl alcohol: this medicinal product contains 480 mg of alcohol (ethanol) in each 10 ml dose.

The amount in 10 ml of this medicine is equivalent to 12 ml of beer and 5 ml of wine.

It can be harmful for alcoholics.

To be considered in pregnant or breastfeeding women, children and high-risk groups such as people suffering from liver disease or epilepsy.

A 10 ml dose of this medicine given to a child aged 12 years and weighing less than or equal to 32 kg would result in an exposure of 15 mg which may cause an increase in blood alcohol concentration (BAC) of about 2.5 mg/100 ml.

Co-administration with medicinal products containing e.g.

Propylene glycol or ethanol can lead to the accumulation of ethanol and induce adverse effects, especially in young children with low or immature metabolic activity.

Propyl and methyl para-hydroxybenzoates, which may cause allergic reactions (even delayed); sodium: this medicinal product contains less than 1 mmol and sodium (23 mg), i.e. essentially sodium-free.

Bronchenol Sedative and Fluidizing mint flavored tablets contains, sucrose: contains 2.08 g of sucrose per dose.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase isomaltase insufficiency should not take this medicine; aspartame: this medicine contains 23 mg aspartame per tablet.

Aspartame is a source of phenylalanine.

It can be harmful if you suffer from phenylketonuria, a rare genetic disease that causes the accumulation of phenylalanine because the body cannot dispose of it properly.

INTERACTIONS:

The medicinal product should not be used at the same time as or within 2 weeks of treatment with monoamine oxidase inhibitor (MAOI) antidepressants, as serious adverse reactions, including serotonin syndrome, have been reported (see section 4.3).

Patients should be advised to consult their physician before taking dextromethorphan in combination with the following medicinal products: concomitant use of dextromethorphan with antidepressants selective serotonin re-uptake inhibitors or tricycle antidepressants may cause serotonin syndrome with changes in human status, hypertension, agitation, myoclonus, hyperreflexisy, diaphoresis, chills and tremors (see sections 4.4 and 4.8); concomitant use of dextromethorphan and alcohol may increase the central nervous system depressive effects of both substances.

CYP2D6 inhibitors: dextromethorphan is metabolised by CYP2D6 and has extensive first-pass metabolism.

Concomitant use of potent inhibitors of the CYP2D6 enzyme may increase the concentrations of dextromethorphan in the body to levels many times higher than normal.

This increases the patient's risk of toxic effects of dextromethorphan (agitation, confusion, tremor, insomnia, diarrhea and respiratory depression) and development of serotonin syndrome.

Potent inhibitors of CYP2D6 are fluoxetine, paroxetine, quinidine and terbinafine.

When used concomitantly with quinidine, plasma concentrations of dextromethorphan are increased up to 20-fold, resulting in increased adverse effects on the agent's central nervous system.

Amiodarone, flecainide and propafenone, sertraline, bupropion, methadone, cinacalcet, haloperidol, perfenazine and thioridazine also have similar effects on the metabolism of dextromethorphan.

If concomitant use of CYP2D6 inhibitors and dextromethorphan is necessary, the patient should be monitored and the dose of dextromethorphan may need to be reduced.

The combination with phenylpropanolamine should be used with caution in subjects with hypertension, heart disease, diabetes, peripheral vasculopathy, prostatic hypertrophy and glaucoma.

Treatment with guaifenesin may result in false positives to the dosage of urinary vanylmandelic acid.

Sedative medicinal products such as benzodiazepines or related medicinal products: the concomitant use of opioids and sedative medicinal products such as benzodiazepines, or related medicinal products, increases the risk of sedation, respiratory depression, coma and death due to the additive depressive effect on the CNS.

The dosage and duration of concomitant treatment should be limited (see section 4.4).

SIDE EFFECTS:

Adverse reactions are listed by organ persists and MedDRA organs with the frequencies Very common (>=1/10), Common (>=1/100, <1/10), Uncommon (>=1/1,000, <1/100), Rare (>=1/10,000, <100 0), very rare (<1/10,000), not known (frequency cannot be estimated from the available data).

Data from clinical studies: The following are the side effects observed in the clinical trials reported with uncommon frequency.

Nervous system disorders: drowsiness.

Ear and labyrinth disorders: vertigo.

Gastrointestinal disorders: gastrointestinal disorders, nausea, vomiting, abdominal disorder.

Post-marketing data: the following side effects are derived from post-marketing reports with unknown frequency.

Psychiatric disorders: confusion, insomnia.

Nervous system disorders: serotonin syndrome (see sections 4.3 and 4.5), agitation, headache.

Gastrointestinal disorders: diarrhea.

Skin and subcutaneous tissue disorders: hypersensitivity, rash, urticaria, angioedema.

Reporting of suspected adverse reactions.

Reporting suspected adverse reactions that occur after the authorisation of the medicinal product is important, as it allows continuous monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are required to report any suspected adverse reactions through the national reporting system at - http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse.

PREGNANCY AND BREASTFEEDING:

Pregnancy and breast-feeding: no clinical data are available for the risk in pregnancy and breast-feeding.

The administration of Sedative and Fluidizing Bronchenol during serious dance and breast-milk lactation should be considered only if the expected benefit to the mother outweighs the risk to the fetus or the child.

Fertility: no data available.