Broncho-Vaxom®

Composition

Active principle

1 capsule for adults contains: 7 mg of lyophilized bacterial lysates of Haemophilus influenzae, Diplococcus pneumonia, Klebsiella pneumoniae and ozaenae, Staphylococcus aureus, Streptococcus pyogenes and viridans, Neisseria catarrhalis.

1 capsule for children contains: 3.5 mg of lyophilized bacterial lysates of Haemophilus influenzae, Diplococcus pneumoniae, Klebsiella pneumoniae and ozaenae, Staphylococcus aureus, Streptococcus pyogenes and viridans, Neisseria catarrhalis.

Excipients

1 capsule contains: antiox. (E 310), glutamate, dye (E 132), excipients for capsule.

Properties/Effects

Immunostimulating agent.

In animals, an increased resistance towards experimental infections, a stimulation of macrophages and B lymphocytes as well as an increase in immunoglobulins secreted by the respiratory mucosal cells have been reported.

In humans, an increase in t e rate of circu ating T lymphocytes, in salivary IgA, in the non specific response to polyclonal mitogens and in the mixed lymphocyte reaction has been observed.

Preclinical safety data:

Extensive toxicity studies have not revealed any toxic effect.

Pharmacokinetics

No experimental model available up to now.

Indications/Possibilities of use

Immunotherapy. Prevention of recurrent infections of the airways and acute infectious exacerbations of chronic bronchitis.

Comedication in the treatment of acute airway infections.

Dosage and method of administration

Preventive treatment and/or consolidation therapy: capsule daily on an empty stomach during 10 consecutive days per month for 3 months.

Treatment of acute episodes: 1 capsule daily on an empty stomach until disappearance of the symptoms (but for at least 10 days). In cases in which antibiotics are needed, the administration of Broncho-Vaxom® should be associated preferably from the start of therapy.

Children aged from 6 months to 12 years: Same treatment schedule as for adults, Broncho-Vaxom® Children containing half the dose of Broncho-Vaxom® Adults.

Note: The capsules Broncho-Vaxom® Children can be opened.

If a child has difficulty in swallowing them, their content may be poured into a drink (fruit juice, milk, etc.).

Limitations for use

Contra-indications

Known hypersensitivity towards the constituents of Broncho-Vaxom®.

Precautions

On the basis of present knowledge, the administration of Broncho-Vaxom® to children aged less than 6 months is not recommended, because of the immaturity of their immune system.

Effects on ability to drive and use machines

Broncho-Vaxom® is presumed to be safe and unlikely to produce an effect.

Pregnancy and lactation

Reproduction studies in animals have not demonstrated any risk to the foetus, but controlled studies in pregnant women are not available. As regards breast-feeding, no specific studies have been performed and no data have been reported up to now.

Undesirable effects

The global incidence of adverse effects revealed in clinical studies is between 3 and 4%. The adverse effects reported are classed below according to their frequency (frequent: ≥ 1 10%; infrequent: 0.1-1%; rare: 0.01-0.1%; very rare: less than 0.01%, including isolated cases).

Undesirable effects (MedDRA classification)					
	Gastrointestinal upsets	**Skin problems**	**Respiratory problems**	**Nervous system problems**	**General problems**
Frequent 1-10%	Diarrhoea			Headaches	
Infrequent 0.1-1%	- Abdominal pain - Nausea - Vomiting	- Exanthema - Urticaria	- Dyspnoea - Cough - Asthma		Tiredness
Rare					- Fever - Allergic reactions

If gastrointestinal or respiratory problems persist, the treatment should be withdrawn.

The treatment should be withdrawn in the event of skin reactions since they may involve an allergic reaction.

• Isolated cases

Pharmacovigilance data reveal a very low incidence of these undesirable effects (less than 0.001%) in a population treated with Broncho-Vaxom®.

Isolated cases of reactions of an immunoallergic nature or not have been reported: purpura with or without thrombocytopenia, dyspnoea with rash and abdominal cramps, aggravation of allergic vasculitis, idiopathic thrombocytopenia, urticaria or generalised exanthema, Quincke's oedema, angioneurotic oedema, severe arthralgia, aggravation of Churg-Strauss syndrome, tachycardia and a feeling of weakness as part of a hypersensitivity syndrome.

One isolated case of Lyell syndrome in a child has been notified among more than 500 million doses of Broncho-Vaxom® prescribed to adults and children. A relationship with the administration of Broncho-Vaxom® was considered to be possible but it was specified that other causes (such as mycoplasma infection) could have contributed to this undesirable effect.

In all, the frequency of undesirable effects observed is estimated as extremely low in view of the very high exposure of the population to this product.

Interactions

No drug interaction is known up to now.

Overdose

No case of overdose is known up to now. Due to the nature of Broncho-Vaxom® and the results of toxicity tests performed in animals, an overdosage seems impossible to reach.

Particular remarks

Incompatibilities

Not known up to now.

Shelf life

Stored in its original packa e, Broncho-Vaxom® has a shelf life of 5years.

Special precautions for storage

The medication should be stored protected from heat (below 30°C).

The medication should not be used after the expiration date printed on the package together with the mention «EXP».

Presentations

Capsules for adults: 10 and 30.

Capsules for children: 10 and 30.

This is a medicament

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consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Supplier/Manufacturer

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OM PHARMA
Meyrin-Geneva Switzerland

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