1. Name of the medicinal product
BRONCHO-VAXOM

2. Qualitative and quantitative composition
1 capsule for adults contains:
Lyophilized bacterial lysates of Haemophilus influenzae, Diplococcus pneumoniae, Klebsiella pneumoniae and ozaenae, Staphylococcus aureus, Streptococcus pyogenes and viridans, Neisseria catarrhalis: 7 mg.

1 capsule for children contains:
Lyophilized bacterial lysates of Haemophilus influenzae, Diplococcus pneumoniae, Klebsiella pneumoniae and ozaenae, Staphylococcus aureus, Streptococcus pyogenes and viridans, Neisseria catarrhalis: 3.5 mg.
For excipients see 6.1.

3. Pharmaceutical form
Capsules.

4. Clinical particulars
4.1. Therapeutic indications
Immunotherapy.

4.2. Posology and method of administration
Oral route.

Adults
Preventive treatment and/or consolidation therapy: 1 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
The capsule can be opened and the content poured into a drink (water, fruit juice, milk, etc.).
Preventive treatment and/or consolidation therapy: 1 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.

4.3. Contra-indications
Hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings and special precautions for use
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.

4.5. Interactions with other medicinal products and other forms of interaction
No drug interaction is known up to now.

4.6. Pregnancy and lactation
No clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.
As regards breast-feeding, no specific studies have been performed and no data have been reported up to now.
Thus, caution should be exercised when prescribing to pregnant or breastfeeding women.

4.7. Effects on ability to drive and use machines
Broncho-Vaxom has no influence on the ability to drive and use machines.
4.8. 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).

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, Quinicke’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.

4.9. Overdose
No case of overdose has been reported. Due to the nature of Broncho-Vaxom and the results of toxicity tests performed in animals, an overdose seems impossible to reach.

5. Pharmacological properties
5.1. Pharmacodynamic properties
Pharmacotherapeutic group: Other respiratory system products, ATC Code: R07AX.

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 the rate of circulating T lymphocytes, in salivary IgA, in the nonspecific response to polyclonal mitogens and in the mixed lymphocyte reaction have been observed.

5.2. Pharmacokinetic properties
No experimental model available up to now.

5.3. Preclinical safety data
Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. Pharmaceutical particulars
6.1. List of excipients
Pregelatinized maize starch, magnesium stearate, propyl gallate (E310), sodium glutamate, mannitol, gelatine, indigotine (E132), titanium dioxide (E171).

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
The medication should not be used after the expira-
tion date printed on the package together with the mention “EXP:”

6.4. Special precautions for storage
To be stored protected from heat (below 30°).
Store in the original package.

6.5. Nature and contents of container
Boxes containing 1 or 3 blisters (aluminium/ PVDC - PVC/PVDC foils) of 10 capsules (blue for adults and blue/white for children).

6.6. Instructions for use/handling
No special requirements.

7. Marketing authorization holder
OM PHARMA, 22, rue du Bois-du-Lan, P.O. Box 84, 1217 Meyrin 2 / Geneva (Switzerland)