SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
BRONCHO-VAXOM® Adults, 7 mg, capsules, hard
BRONCHO-VAXOM® Children, 3.5 mg, capsules, hard

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 hard capsule for adults contains:
Lyophilized bacterial lysates of Haemophilus influenzae, Streptococcus (Diplococcus) pneumoniae, Klebsiella pneumoniae ssp. pneumoniae and ssp. ozaenae, Staphylococcus aureus, Streptococcus pyogenes and sanguinis (viridans), Moraxella (Branhamella/Neisseria) catarrhalis: 7 mg.

1 hard capsule for children contains:
Lyophilized bacterial lysates of Haemophilus influenzae, Streptococcus (Diplococcus) pneumoniae, Klebsiella pneumoniae ssp. pneumoniae and ssp. ozaenae, Staphylococcus aureus, Streptococcus pyogenes and sanguinis (viridans), Moraxella (Branhamella/Neisseria) catarrhalis: 3.5 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Broncho-Vaxom Adults
Capsule, hard
Opaque capsules with a blue capsule body and a blue cap.

Broncho-Vaxom Children
Capsule, hard
Opaque capsules with a white capsule body and a blue cap.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Immunotherapy.
Prevention of recurrent infections of the airways and acute infectious exacerbations of chronic bronchitis.
Co-medication in the treatment of acute airway infections.
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 Adults should be associated preferably from the start of therapy.

Children (aged from 6 months to 12 years)

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 Children should be associated preferably from the start of therapy.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Broncho-Vaxom can cause hypersensitivity reactions. If allergic reactions or signs of intolerance occur, the treatment must be stopped immediately.

Paediatric population

On the basis of present knowledge, the administration of Broncho-Vaxom to children aged less than 6 months is not recommended. Safety and effectiveness in paediatric patients below the age of 6 months have not been established.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interaction is known up to now.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Broncho-Vaxom in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
As a precautionary measure, it is preferable to avoid the use of Broncho-Vaxom during pregnancy.

**Breast-feeding**
No specific studies have been performed and no data have been reported up to now. The product should be administered cautiously during breast-feeding.

**Fertility**
In animal studies there is no effect of Broncho-Vaxom on fertility index.

### 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

**Very common:** ≥1/10  
**Common:** ≥1/100 to <1/10  
**Uncommon:** ≥1/1,000 to <1/100  
**Rare:** ≥1/10,000 to <1/1,000  
**Very rare:** <1/10,000  
**Not known:** cannot be estimated from the available data

**Immune system disorders**  
*uncommon:* hypersensitivity (rash erythematosus, rash generalised, erythema, oedema, eyelid oedema, face oedema, peripheral oedema, swelling, face swelling, pruritus, generalised pruritus, dyspnoea).

**Nervous system disorders**  
*not known:* headache

**Respiratory, thoracic and mediastinal disorders**  
*common:* cough

**Gastrointestinal disorders**  
*common:* diarrhoea, abdominal pain  
*not known:* nausea, vomiting

**Skin and subcutaneous tissue disorders**  
*common:* rash  
*not known:* urticaria, angioedema

**General disorders and administration site conditions**  
*not known:* pyrexia, fatigue

In case of lasting gastrointestinal disorders, treatment should be interrupted.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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 overdosage seems unlikely to happen.

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 non-specific 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
Non-clinical 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
Starch (pregelatinised), magnesium stearate, propyl gallate (E 310), sodium glutamate, mannitol
Capsule shell’s composition: gelatin, indigotine (E 132), titanium dioxide (E 171).
6.2 Incompatibilities
Not applicable.

6.3 Shelf life
5 years

6.4 Special precautions for storage
Store below 25°C.
Store in the original package.

6.5 Nature and contents of container
Pack of 10 capsules, hard (1 blister of 10 capsules)
Pack of 30 capsules, hard (3 blisters of 10 capsules each)
The capsules are blister packed, with one side made from PVC/PVDC film and the other from aluminium foil coated with PVDC.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
OM PHARMA S.A.
Rua da Industria, 2 – Quinta Grande
2610-088 Amadora – Lisbon - Portugal

8. MARKETING AUTHORISATION NUMBERS
Broncho-Vaxom Adults: MA121/00201
Broncho-Vaxom Children: MA121/00202

9. DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
31st October 2006/ 9th October 2012

10. DATE OF THE REVISION OF THE TEXT
29th February 2016