Broncho-Vaxom®

Adults/Children

COMPOSITION

Active substance:

Combination of bacterial lysates corresponding to lyophilized bacterial lysates of: *Haemophilus influenzae, Streptococcus pneumoniae, Klebsiella pneumoniae ssp., pneumoniae and ozaenae, Staphylococcus aureus, Streptococcus pyogenes and sanguinis, Moraxella (Branhamella) catarrhalis*.

Excipients of the capsules:

Anhydrous propyl gallate, Monosodium glutamate (corresponding to anhydrous sodium glutamate), Pregelatinised starch, Magnesium stearate, Mannitol, color.: indigotin (E 132), titanium dioxide (E171).

PHARMACEUTICAL FORMS AND QUANTITIES OF THE ACTIVE SUBSTANCE PER UNIT

Adult capsules: 7 mg of lyophilized bacterial lysates. Child capsules: 3.5 mg of lyophilized bacterial lysates.

INDICATION/POSSIBILITIES FOR USE

Immunotherapy.

Prevention of recurrent respiratory tract infections and acute infective exacerbations of chronic bronchitis.

POSOLOGY/METHOD OF ADMINISTRATION

Adults and adolescents aged over 12:

The prophylactic treatment cycle for recurrent respiratory tract infections is 1 capsule Broncho-Vaxom Adults daily on an empty stomach during 10 consecutive days per month for 3 consecutive months.

Broncho-Vaxom is not indicated for the treatment of acute respiratory infections but instead for the prevention of their recurrence.

Prophylactic treatment can be initiated during the acute phase of respiratory tract infections, in combination with other treatments.

Children aged from 6 months to 12 years:

The prophylactic treatment cycle for recurrent respiratory tract infections is: one capsule of Broncho-Vaxom Children daily, to be taken on an empty stomach, for 10 consecutive days per month, over 3 consecutive months. Broncho-Vaxom is not indicated for the treatment of acute respiratory infections but instead for the prevention of their recurrence. Prophylactic treatment can be initiated during the acute phase of respiratory tract infections in combination with other treatments.

Note:

If the child has difficulty swallowing the capsule, it can be opened and the content poured into a sufficient quantity of water, fruit juice or milk. The mixture will dissolve with gentle stirring.

Patients are advised to drink the entire mixture within a few minutes and to stir it well just before drinking.

Special dosage instructions

Patients with hepatic or renal disorders

There are no clinical data on the efficacy and safety of Broncho-Vaxom in these patients.

Children aged under 6 months:

Limited data from clinical studies are available on the use of Broncho-Vaxom in children under 6 months of age. As a precautionary measure, the use of Broncho-Vaxom in children under 6 months of age is not recommended.

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients in accordance with the composition.

WARNING AND PRECAUTIONS

Broncho-Vaxom may cause hypersensitivity reactions. If allergic reactions or signs of intolerance occur, treatment should be stopped immediately.

No data from clinical studies are available to demonstrate that the use of Broncho-Vaxom can prevent pneumonia. Therefore, the administration of Broncho-Vaxom to prevent pneumonia is not recommended.

INTERACTIONS

No drug interaction is known to date.

PREGNANCY AND LACTATION

There is limited clinical data regarding use in pregnant women. Animal studies have not shown any direct or indirect toxicity affecting pregnancy, embryonic development, foetal development and/or post-natal development. As a precautionary measure, it is preferable to avoid the use of Broncho-Vaxom during pregnancy.

Regarding breast-feeding, no specific studies have been conducted and no data have been reported. Caution is advised when breast-feeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No relevant studies have been carried out, but it is unlikely that Broncho-Vaxom will have an influence on the ability to drive and use machines.

UNDESIREABLE EFFECTS

The identified undesirable effected are listed below according to the MedDRA classification, depending on their frequency and the system organ classes concerned.

The frequencies are indicated in descending order in accordance with the following convention:

– Very common (≥ 1/10)
– Common (≥1/100 to <1/10)
– Uncommon (≥1/1,000 to <1/100)
– Rare (≥1/10,000), including isolated cases
– Not known (reported after authorization). Reported voluntarily by a population of undetermined size, it is not possible to provide a viable estimate.

Immune system disorders
Uncommon: hypersensitivity (rash, urticarial, swelling, swelling of the eyelids/face, generalized pruritus, dyspnea)
Not known: angioedema

Nervous system disorders
Common: headaches

Respiratory, thoracic and mediastinal disorders
Common: coughing

Gastrointestinal disorders
Common: diarrhea, abdominal pain
Uncommon: nausea, vomiting

Skin and subcutaneous tissue disorders
Common: rash
Uncommon: erythema, erythematous rash, general skin rash, pruritus

General disorders
Uncommon: fatigue, peripheral swelling
Rare: pyrexia

In cases of persistent gastrointestinal or respiratory disorders, treatment should be discontinued.
If you notice any side effects, contact your doctor, pharmacist. This is particularly important in regard to side effects that are not listed in this package leaflet.

OVERDOSE
No cases of overdose have been reported.

PROPERTIES/EFFECTS
ATC code: R07AX – Other respiratory system products.

In animals, increased resistance to experimental infections, 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.

PHARMACOKINETICS
Absorption
The active ingredient of OM-85 is a bacterial extract comprising lyophilised fractions of 21 inactivated bacterial strains belonging to eight different species: *Haemophilus influenzae, Streptococcus pneumoniae, Klebsiella pneumoniae ssp. pneumoniae and ssp. ozaenae, Staphylococcus aureus, Streptococcus pyogenes and sanguinis, Moraxella (Branhamella) catarrhalis*. Due to the nature of the product, a conventional pharmacokinetic study cannot be performed, mainly because of the multiplicity of components and the lack of a suitable analytical method. No experimental model is currently available.

Distribution
No data available.

Metabolism
No data available.
Elimination
No experimental model is available.

PRECLINICAL DATA
Extensive toxicity studies have not revealed any toxic effect.

SHELF LIFE
Store in its original package, out of sight and reach of children.
Broncho-Vaxom has a shelf life of 5 years.

SPECIAL REMARKS
Special precautions for storage
Do not store above 30°C.
Do not use this medicinal product after the expiry date which is stated on the container after “EXP”.

Comments regarding handling
No particular comments.

Legal supply status
On medical prescription only

PRESENTATION
Capsules for adults:
10 capsules
Reg. N°:

Capsule for children:
10 capsules
Reg. N°:

Manufactured by:

OM Pharma SA
22, rue du Bois-du-Lan
1217 Meyrin Switzerland

BD-BV 0522
2055400820

Date of revision of the text April 2021

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Product: Broncho-Vaxom capsules

Country: Bangladesh

Item code: 2055400820	**Version code:** BD-BV 0522
Dimensions: 190 x 297 mm	**Date:** 23-06-2022 v1
Cutter guide:	**Laetus code:** 170
Colors: ■ Black	
Fonts: Arial (mimium 10 pts)	