SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medical product
RESPIVAX Adults 50 mg tablets.

2. Qualitative and quantitative composition
Active substance
Each tablet of Respivax contains 50 mg lyophilized killed bacterial cultures of the following types of microbes: *Streptococcus pneumoniae, Branchamella catarrhalis,* Group A *Streptococcus pyogenes, Haemophilus influenzae type b, Staphylococcus aureus, Klebsiella pneumoniae* in quantity corresponding to 1,25 x 10^9 cells from each type.

Auxiliary substances in g for Respivax 50 mg tablets

Respivax	**50 mg**
Microcrystalline cellulose	0,066
Wheat starch	0,065
Anhydrous colloidal silicon dioxide	0,006
Povidone	0,010
Magnesium stearate	0,003
Dextran 40 included in the composition of the active substance as stabilizer.	0,030

For the full list of the auxiliary substances, see 6.1.

3. Pharmaceutical form
Tablets.

4. Clinical data
4.1. Therapeutic indications
Respivax is indicated for peroral immunotherapy and immunoprophylaxis of nonspecific diseases of the respiratory system and has a very good effect in the treatment of children and adults, suffering from recurrent or chronic infections of the respiratory tract:
- acute bronchitis and tracheobronchitis
- chronic and recurrent bronchitis and tracheobronchitis
- acute and chronic tonsillitis, pharyngitis and laryngitis
- acute and chronic rhinitis, sinuitis and ottitis
- recurrent bronchopneumonia
- infections of the respiratory system that are resistant to antibiotic therapy
- infections of the respiratory system accompanied by hypersensitivity to antibiotics or other chemotherapeutics
- immune system suppression resulting from various diseases
- infectious bronchial asthma
- the application of Respivax during the autumn/winter season is very suitable before or during influenza epidemics, when its prophylactic and therapeutic effect upon the developing secondary bacterial infections is markedly beneficial.

4.2. Dosage and mode of administration
For immunotherapy and immunoprophylaxis Respivax Adult is applied in adults with a daily dose of 50 mg as follows:

Treatment (Immunotherapy) – 1 tablet per day for 30 days, in the morning before breakfast; maintenance therapy – for a long-lasting effect of treatment the taking of 1 tablet of Respivax per day, in the morning before breakfast, is recommended for 20 days during three consecutive months. This course of treatment may be repeated after 5-6 months.

Prophylactic course (Immunoprophylaxis) - 1 tablet of Respivax per day, in the morning before breakfast, is recommended for 20 days during three consecutive months.

It is recommended that the prophylaxis starts from October.

In cases of severe suppression of the immune system resulting from various diseases, including malignant, the treatment course may be prolonged with the patients taking 1 tablet of Respivax in the morning before breakfast without interruption for 3-6 months.

4.3. Contraindications
Respivax is contraindicated in the cases of autoimmune diseases with increased production of antibodies.

4.4. Special warnings and precautions
Respivax contains minimum amount of formaldehyde /from 0,001 to 0,1 mg/tabl./. The medicament contains wheat starch which could be dangerous for people with coeliac disease.

4.5. Interactions with other medical products and other modes of interaction
No incompatibility with other medical products was observed. Respivax can be combined with any other treatment, including antibiotic therapy. It is suitable for repeated use with no risk of dependence.

4.6. Fertility, pregnancy and breastfeeding
Respivax is not recommended during the first trimester of pregnancy.

4.7. Effects on the ability to drive and use machines
Respivax has no effect on the ability to drive and use machines.

4.8. Adverse reactions
To date, no adverse reactions were observed. Clinical results show very good tolerance.

4.9. Overdosage
No reports for cases of overdosage.

5. Pharmacological characteristics

5.1. Pharmacodynamic characteristics
Mechanism of action – Respivax is a polybacterial immunostimulator, which enhances the natural resistance of the organism and the specific immunity to various infections of the respiratory tract by stimulation of the humoral and cellular factors of the immune system. It has been proven to have stimulating effect upon the cells of the immune system, the intestines and the mesenterium and in considerable degree, upon the lymphoid formations in the lungs located peribronchially.
Pharmacological group: ATC, code L03AX 00

6. Pharmaceutical data

6.1. List of the auxiliary substances

Respivax	50 mg	Function
Microcrystalline cellulose	0,066	diluent
Wheat starch	0,065	diluent
Anhydrous colloidal silicon dioxide	0.006	desiccant
Povidone	0,010	binder
Magnesium stearate	0,003	lubricant
Dextran 40 included in the composition of the active substance	0.030	stabilizer during lyophilization

6.2. Incompatibilities
No physicochemical incompatibilities.

6.3. Shelf Life
3 years.

6.4. Special storage conditions
Store at temperatures below 25° C protected from light. Keep out of reach of children.

6.5. Package
Respivax 50 mg is packaged in polyvinyl chloride and aluminum foil blister packs of 10 tablets each. Three blister packs are put in a cardboard box together with a package insert.

6.6. Disposal precautions
No special requirements.

7. Marketing authorization holder
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Bulgaria
Tel. +359 2 944 61 91
Fax +359 2 943 34 55
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8. Product license number
II-14329/04.10.2006

9. Date of first marketing authorization
Date of first marketing authorization: 18 December 1987.
Date of last license renewal: 04 October 2006.
Registration number 20010516.

10. Last update of the text
03.2011