

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medical product

RESPIVAX Children 25 mg tablets.

2. Qualitative and quantitative composition

Active substance

Each tablet of Respivax contains 25 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 $0,625 \cdot 10^9$ cells from each type.

Auxiliary substances in g for Respivax 25 mg tablets

Respivax	25 mg
Microcrystalline cellulose	0,052
Wheat starch	0,051
Anhydrous colloidal silicon dioxide	0,003
Povidone	0,007
Magnesium stearate	0,002
Dextran 40 included in the composition of the active substance as stabilizer.	0,015

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, sinusitis and otitis
- 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

The use of Respivax in children under 3 years of age is not recommended because of insufficient safety data. For immunotherapy and immunoprophylaxis Respivax is applied in children between 3 and 14 years of age with a daily dose of 25 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 L03 00

6. Pharmaceutical data

6.1. List of the auxiliary substances

Respivax	25 mg	Function
Microcrystalline cellulose	0,052	diluent
Wheat starch	0,051	diluent
Anhydrous colloidal silicon dioxide	0.003	desiccant
Povidone	0,007	binder
Magnesium stearate	0,002	lubricant
Dextran 40 included in the composition of the active substance	0.015	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° protected from light. Keep out of reach of children.

6.5. Package

Respivax 25 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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8. Product license number

II-14328/04.10.2006

9. Date of first marketing authorization

Date of first marketing authorization: 18 December 1987.

Date of last license renewal: 04 October 2006.

Registration number 20010515.

10. Last update of the text

03.2011