

Package leaflet: Information for the patient

Polyvaccinum mite, nasal drops, suspension Non-specific bacterial vaccine

Inactivated bacteria: *Staphylococcus aureus* 50 million cells, *Staphylococcus epidermidis* 50 million cells, *Streptococcus salivarius* 10 million cells, *Streptococcus pneumoniae* 10 million cells, *Streptococcus pyogenes* 10 million cells, *Escherichia coli* 20 million cells, *Klebsiella pneumoniae* 10 million cells, *Haemophilus influenzae* 10 million cells, *Corynebacterium pseudodiphtheriticum* 20 million cells, *Moraxella catarrhalis* 10 million cells/ 1 ml

Read all of this leaflet carefully before you start using this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Polyvaccinum mite is and what it is used for
2. What you need to know before you use Polyvaccinum mite
3. How to use Polyvaccinum mite
4. Possible side effects
5. How to store Polyvaccinum mite
6. Contents of the pack and other information

1. What Polyvaccinum mite is and what it is used for

Polyvaccinum mite, nasal drops is a bacterial vaccine, which protects against recurrent upper respiratory tract infections. The vaccine stimulates immune system, because it contains killed bacteria which most commonly cause upper respiratory tract infections or assist upper respiratory tract inflammations.

Polyvaccinum mite should be used according to the dosage scheme for children and adults:

- to prevent recurrent upper respiratory tract infections (prophylactic treatment),
- in supportive treatment of upper respiratory tract infections (therapeutic treatment).

Dosage scheme is in section 3.

2. What you need to know before you use Polyvaccinum mite

Do not use Polyvaccinum mite :

- if you are allergic to the active substances or any of the other ingredients of this vaccine (listed in section 6),
- if you have:
 - infectious diseases,
 - circulatory failure,
 - renal or liver diseases,
 - proliferative diseases of the haematopoietic system (cancer of haematopoietic system),
 - systemic diseases (diseases involving several types of tissues and organs or involving whole body),

- if you use immunosuppressive preparations (preparations which inhibit immune system response).

Do not start the treatment, if you are during the acute phase of the disease.

Warnings and precautions

The vaccination should be preceded by a clinical examination and a review of medical history with special regard to your general health condition and previous vaccinations. This precaution allows to anticipate possible risk of side effects and to change the dosage scheme.

Keep special caution if you notice any side effects described in section 4 or any other worrying reactions after the previous dose of the vaccine. The vaccine may be used during infection if the vaccination started before the occurrence of the infection.

Other medicines and Polyvaccinum mite

In patients undergoing immunosuppressive treatment (inhibiting the activity of the immune system) immunological response may be reduced. In such situations a doctor may decide to postpone vaccination until the end of therapy.

The vaccine may be used during antibiotic therapy, if a doctor considers administration of antibiotic necessary.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

No data is available on the effects of the vaccine use during pregnancy and breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice using this medicine.

Driving and using machines

The vaccine has no or negligible influence on the ability to drive and use machines.

3. How to use Polyvaccinum mite

Administer the vaccine intranasally, measuring the appropriate amount of drops with the dropper.

Shake well before each use.

Prior to administration, check the vaccine expiry date stated on the packaging.

Do not use the vaccine after the expiry date.

Undergo the treatment twice a year in periods preceding the most adverse weather conditions: in January-February and in August-September, over the period of at least 2 years. Administer the vaccine every day for 6 weeks.

If upper respiratory tract infection occurs during the treatment, continue to administer the vaccine without increasing the dose.

Do not start the treatment during acute phase of disease.

Dosage

If your doctor has not told you otherwise, you should use the complete vaccination cycle according to the dosage scheme presented in the table:

Age group	Number of drops per single administration				Number of drops per day	The administration period (in weeks)
	In the morning		In the evening			
	Nasal cavity		Nasal cavity			
	Right	Left	Right	Left		
Children from 6 months to 3 years	-	-	-	1	1	Week I
	-	-	1	1	2	Weeks II and III
	1	1	1	1	4	Weeks IV, V, VI
Children from 3 to 7 years	-	-	1	1	2	Week I
	1	1	1	1	4	Weeks II and III
	1	1	2	2	6	Weeks IV, V, VI
Children over 7 years and adults	1	1	1	1	4	Weeks I and II
	1	1	2	2	6	Weeks III and IV
	2	2	2	2	8	Weeks V and VI

The dosage depends on your individual reaction. The doctor can extend the administration period of lower doses if you have known hypersensitivity (allergy) to bacterial antigens contained in the vaccine.

The best protection against recurrent upper respiratory tract infections is achieved after taking a complete vaccination cycle according to the dosage scheme.

If you use more Polyvaccinum mite than you should

If your doctor has not told you otherwise, you should continue the dosage according to the scheme.

If you forget to use Polyvaccinum mite

In case of doubt, please contact with doctor or pharmacist.

If you stop using Polyvaccinum mite

If you have any further questions on the use of this vaccine, ask your doctor or pharmacist.

4. Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

Frequency not known (frequency cannot be estimated from the available data):

- local reaction: irritation of nasal mucous membrane – burning sensation, itching.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, tel.: +48 22 49 21 301, faks: +48 22 49 21 309, e-mail: ndl@urpl.gov.pl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Polyvaccinum mite

Store in a refrigerator (2°C - 8°C).

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Polyvaccinum mite contains

The active substances of the vaccine are inactivated (killed) bacteria:

Staphylococcus aureus, *Staphylococcus epidermidis* 50 million cells/1 ml of each

Escherichia coli, *Corynebacterium pseudodiphtheriticum* 20 million cells/1 ml of each

Streptococcus salivarius, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Klebsiella pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis* 10 million cells/1 ml of each

The other ingredients are: phenol, sodium chloride, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dehydrate and water for injections.

What Polyvaccinum mite looks like and contents of the pack

The vaccine is opalescent, colorless suspension.

The packaging: the one bottle containing 10 ml of suspension with a dropper.

Marketing Authorisation Holder and Manufacturer

IBSS BIOMED S.A.

Al. Sosnowa 8

30-224 Krakow, Poland

Tel: +48 12 37 69 200

Fax: +48 12 37 69 205

e-mail: marketing@biomed.pl

This leaflet was last revised in: March 2014