Package leaflet: Information for the user

Pseudovac, solution for injection
Polyvalent vaccine against blue pus bacterium *Pseudomonas aeruginosa.*
1 ml of the vaccine contains *Pseudomonas aeruginosa* antigens from 7 immunotypes (according to Fisher, Devlin, Gnabasik classification) immunotype 1 - 0.125 ml, immunotype 2 - 0.125 ml, immunotype 3 - 0.125 ml, immunotype 4 - 0.125 ml, immunotype 5 - 0.125 ml, immunotype 6 - 0.125 ml, immunotype 7 - 0.125 ml, immunotype 3,7 - 0.125 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, pharmacist or nurse.
– 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pseudovac is and what it is used for

Pseudovac is a bacterial vaccine which stimulates immunity against blue pus bacterium *Pseudomonas aeruginosa*. The vaccine contains antigens of killed *Pseudomonas aeruginosa* strains, which represent 7 clinically important immunotypes.

Pseudovac is used in children and adults in case of the risk of infection and septicaemia (sepsis) caused by *Pseudomonas aeruginosa* with special consideration for patients with extensive burns.

Pseudovac is used:
- in prophylactic treatment: in order to achieve active immunity against infections caused by *Pseudomonas aeruginosa*,
- in therapeutic treatment: in case of existing infections caused by *Pseudomonas aeruginosa*, in order to augment specific immunity and lower the risk of development of bacteraemia (the presence of bacteria in the blood) and septicaemia (sepsis).

Pseudovac complies with the requirements of the European Pharmacopoeia and the World Health Organization (WHO).

2. What you need to know before you use Pseudovac

Do not use Pseudovac:
– if you if you are allergic to active substances or any of the other ingredients of this vaccine (listed in section 6). Allergy symptoms may include: itchy rash, dyspnoea, swelling of the face and tongue,
– during acute febrile illnesses which are not caused by *Pseudomonas aeruginosa*. A mild infection, such as a common cold, should not be a contraindication, but you should inform your doctor first,

- in case of chronic diseases in exacerbation phase. In these cases vaccination should be postponed until the exacerbation phase subsides,
- if you are pregnant or during breast-feeding.

If there are any contraindications for vaccination with Pseudovac, the doctor should assess the risk associated with the vaccine administration in relation to the risk of infection

Warnings and precautions
The use of Pseudovac should be preceded by a medical examination and a review of general health condition and previous vaccinations.
Before each subsequent dose, patient should be asked, if any worrying reactions has occurred after previous vaccine dose. This precaution allows to anticipate the possible risk of side effects after vaccine administration.

A special care should be taken if side effects described in section 4, or any other worrying reactions appeared after a previous dose of Pseudovac.

For safety reasons, the vaccinee should remain under medical supervision for 30 minutes after the vaccination.

Other medicines and Pseudovac
In patients undergoing immunosuppressive treatment (inhibiting the activity of the immune system) or with immune deficiency, immunological response may be reduced. In such situations the doctor may decide to postpone vaccination until the end of therapy

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

Pregnancy and breast-feeding
Do not use.

Driving and using machines
No studies on the effects the vaccine on the ability to drive and use machines have been performed.

3. How to use Pseudovac

Always use this vaccine exactly as your doctor has told you. Check with your doctor if you are not sure.

Pseudovac will be given by a doctor or nurse as an intramuscular injection. The vaccine should never be given intravenously.

Dosage:

If your doctor does not tell you otherwise, it is recommended to administer Pseudovac to children and adults according to the following scheme:

Day	Vaccine dose
1	0.2 ml
4	0.4 ml
6	0.6 ml
8	0.8 ml
10	1.0 ml

In case of patients with burns the vaccine should be used as early as possible, on 1 – 3 day since the burning incident and given scheme should be strictly followed.

In case of occurrence of strong local or systemic reactions tell your doctor, who can decide to elongate the intervals between subsequent doses or to repeat the last given dose, reaching consistently the 1.0 ml dose.

If you use more Pseudovac than you should
No data available on the overdose.
In case of taking more Pseudovac than you should, tell your doctor, pharmacist or nurse immediately.

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

4. Possible side effects

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

Frequency not known (cannot be estimated from the available data):
– headache
– redness, swelling and/or pain at injection site
– fever
– malaise.
These symptoms usually subside within 24 – 48 hours.

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.: 22 49-21-301, fax: 22 49-21-309, e-mail: ndl@urpl.gov.pl.
Adverse reactions can also be reported to the Marketing Authorisation Holder. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pseudovac

Store in a refrigerator (2°C - 8°C).
Do not freeze. In case of freezing, discard the vaccine.
Keep the 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 Pseudovac contains
The active substances of the vaccine are *Pseudomonas aeruginosa* antigens from 7 immunotypes (according to Fisher, Devlin, Gnabasik classification).
One milliliter of the vaccine contains:
– immunotype 1 – 0.125 ml
– immunotype 2 – 0.125 ml
– immunotype 3 – 0.125 ml
– immunotype 4 – 0.125 ml
– immunotype 5 – 0.125 ml
– immunotype 6 – 0.125 ml

– immunotype 7 – 0.125 ml
– immunotype 3,7 – 0.125 ml

The other ingredient is phenol.

What Pseudovac looks like and contents of the pack
The vaccine is a clear, straw - colored solution in the glass ampoules.
The packaging contains 5 ampoules 1 ml each.

Marketing Authorization Holder and Manufacturer
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The following information is intended for healthcare professionals only:

Pseudovac administration
Shake well before use. The vaccine is a clear, straw - colored solution.
The vaccine should be visually inspected for any foreign particulate matter and/or abnormal changes in physical appearance. In the event of any change, the vaccine should not be used.

Administer intramuscularly.

Do not administer intravenously! Make sure that the needle is not introduced into a blood vessel.

Note: Due to the risk of anaphylactic shock associated with vaccination, the vaccination room should be equipped with a standard shock-controlling set.

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