

**Please read carefully before use.**

## **PAVIVAC**

(Virus parotitidis vivum attenuatum)

Powder for solution for injection

### **Registration decision holder**

### **Manufacturer**

**SEVAPHARMA a.s.**

### **Composition**

1 dose of the lyophilized vaccine (0.7 ml) contains:

#### **Active substance:**

Virus parotitidis vivum attenuatum (Jeryl Lynn)                      not less than  $5 \times 10^3$  CCID<sub>50</sub>

#### **Excipients:**

Human serum albumin

Saccharose

Gelatine

Neomycin sulphate

The solvent for Pavivac contains:

Potassium dihydrogenphosphate

Sodium hydrogenphosphate dihydrate

Water for injections

### **Indication group**

Immunopreparation, vaccine

### **Characteristics**

PAVIVAC is a lyophilized live vaccine against mumps, prepared by the propagation of further attenuated Jeryl Lynn strain of the mumps virus on the primary cultures of canine kidney cells.

### **Mechanism of action**

The attenuated virus contained in the vaccine, actively propagates in a vaccinated organism and induces infectious non-contagious immunization process. Clinical studies have shown that after the administration of one dose of the vaccine to susceptible subjects, the antibody response against the mumps virus in virus neutralization test is below a minimal positive titre

of 1:2 in more than 70 % of vaccinated subjects and under a minimal positive titre of 1:1 in 91 % of the vaccinated subjects. After the administration of the second dose of vaccine at a minimal interval of 6 months following the first dose, 100 % antibody response is achieved (titre is equal to or higher than 1:2) against the mumps virus with a marked increase in existing titres of virus-neutralizing antibodies.

### **Indications**

The vaccine is used for the specific prevention of mumps in humans from the 15<sup>th</sup> month of age. The vaccine does not provide protection if applied after exposure to the genuine disease. The vaccination is recommended, apart from common practice, in children with treated inactive or active tuberculosis, with cystic fibrosis and chronic well-compensated cardiac and pulmonary diseases.

### **Contraindications**

- febrile diseases followed by convalescence (2 weeks);
- active untreated tuberculosis;
- therapy with ACTH, corticosteroids, radiation, alkylating agents or antimetabolites,
- proven severe disorder of immunity;
- leukemia, lymphoma or other malignant neoplasms affecting bone marrow or lymphatic system;
- hypersensitivity to any components of the vaccine (e.g. neomycin, proteins of canine hair);
- in the case of a suspected organic affection of the CNS the vaccination can be indicated after consultation with a neurologist;
- pregnancy;
- it should not be administered 4 weeks before or after the administration of other live vaccines with the exception of vaccine against poliomyelitis which may be applied concurrently in healthy children;
- it should not be administered 3 months after blood transfusion, after administration of plasma or human immunoglobulin.

A delay of 5 months is recommended if the applied dose of immunoglobulin is higher than 10 mg/kg.

### **Undesirable effects**

After the vaccination there are mostly no clinical symptoms in the vaccinated subjects. Elevated temperature and swelling in the area of parotid glands have been observed rarely. No post-vaccination meningitis or meningo-encephalitis have been reported until now in the children vaccinated with the preparations containing the Czech attenuated strain of parotitis virus, i.e. their potential frequency is lower than 1:3,900,000.

### **Interactions**

To preclude inactivation of viruses contained in the vaccine:

- 1) caused by maternal antibodies transferred to the child through placenta, the vaccination is carried out until the child has lived up to the 1<sup>st</sup> day of the 15<sup>th</sup> month of age;

- 2) caused by specific antibodies, the vaccine is not administered for 3 month-period after blood transfusion, plasma or human immunoglobulin administration. If the administered immunoglobulin dose was higher than 10 mg/kg of body weight, the vaccination is recommended to perform not earlier than 5 months after the immunoglobulin administration.

Owing to possible interference from other viruses, it is not recommended to administer the vaccine within the 4 month-period before or after other live viral vaccines were administered except the poliomyelitis vaccine that can be administered concurrently in healthy children.

### **Pregnancy and breast feeding**

Pregnant women should not be vaccinated. It is necessary to preclude pregnancy for a period of three months following the vaccination in susceptible women. No information is available on the excretion of viruses contained in the vaccine into human breast milk. The vaccine should be administered to breastfeeding women with caution.

### **Posology and method of administration**

The first dose of the vaccine should be administered to children not before the 1<sup>st</sup> day of the 15<sup>th</sup> month of age. Booster vaccination should be applied after 6 to 10 months following the primary vaccination, in justified cases later.

The solvent for PAVIVAC is used for reconstitution of the lyophilized vaccine.

The vaccine is administered subcutaneously, preferably into peripheral side of the upper part of the arm in a volume of 0.7 ml using disposable syringes after the puncture site has been disinfected with an approved disinfection solution and the used disinfectant has dried up. After vaccination the vaccinated person should remain for at least 30 minutes under medical surveillance.

***The vaccine must not be applied intravenously!***

*Preparation of the solution:*

Dissolve the vaccine with the solvent for PAVIVAC immediately before vaccination. Inject the content of one solvent-containing ampoule (1.4 ml) into the ampoule containing two doses of the lyophilized vaccine. Shake carefully the ampoule with lyophilized preparation to ensure thorough mixing of vaccine that dissolves within one minute to produce a clear solution of yellow-orange to orange-red colour. Protect the liquid vaccine from light and temperature higher than + 8 °C.

*Warning:* Do not use the intact ampoules if contain a red to violet coloured lyophilizate.

### **Caution**

The liquid vaccine should not be used later than 5 hours after dissolution provided that it has been kept at 2 °C to 8 °C, protected from light.

Once opened, the ampoule must not be transported!

It is necessary to ensure that pregnancy is ruled out in vaccinated women for a period of three months following the vaccination

Although no allergic reaction has yet been reported, vaccine skin test is recommended to carry out in patients with proven significant hypersensitivity to canine proteins. The occurrence of hypersensitivity is lower than 1 over 10,000,000.

## Storage

Store the ampoule with lyophilized vaccine at a temperature 2 °C to - 8 °C. Store the ampoules in the paper box to protect the preparation from light.

Protect from freezing.

After dissolving, store the liquid vaccine at a temperature 2 °C to 8 °C, protected from light, and administer within 5 hours following the dissolution at the latest.

## Warning

Do not use the preparation after expiry date stated on the package!

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

Keep the preparation out of reach and sight of children!

## Packing

5 x 2 doses + 5 x 1.4 ml solvent for PAVIVAC

1 x 2 doses + 1 x 1.4 ml solvent for PAVIVAC

## The date of the last revision:

June 16, 2008

