

TRIVIVAC

(Vaccinum morbillorum, parotitidis et rubellae vivum)

Powder and solvent for solution
for injection



Composition

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

Active substances

Virus morbillorum vivum attenuatum (Schwarz)
not less than 3.0 log CCID₅₀
Virus parotitidis vivum attenuatum (Jeryl Lynn)
not less than 3.7 log CCID₅₀
Virus rubellae vivum attenuatum (RA 27/3)
not less than 3.0 log CCID₅₀

Excipients

Human serum albumin
Saccharose
Gelatin
Neomycin sulphate

Solvent for TRIVIVAC contains

Potassium dihydrogen phosphate
Sodium hydrogen phosphate dihydrate
Water for injections

Pharmacotherapeutical group

Viral vaccines

Characteristics and pharmacokinetic data

TRIVIVAC is a lyophilized mixture of live vaccines against measles, mumps and rubella. The measles constituent of vaccine is prepared by the propagation of further attenuated

strain Schwarz of the virus of measles in the primary cultures of dog kidney cells in synthetic medium H-199. The mumps constituent of vaccine is prepared by the propagation of further attenuated Jeryl Lynn strain of the virus of mumps in the primary cultures of dog kidney cells in synthetic medium H-199. The rubella constituent of vaccine is prepared by the propagation of attenuated strain Wistar RA 27/3 of the virus of rubella in the cultures of human diploid cells Wistar 38 in Earle synthetic medium.

The administration of one dose induces in susceptible subjects 100 % antibody response to measles virus, 98 % to rubella virus and 70 % to mumps virus. By the administration of the second dose 100 % antibody response to the viruses of measles, rubella and mumps is reached.

Mechanism of action

The attenuated viruses contained in the vaccine actively propagate in the vaccinated organism and induce infectious non-contagious immunization process.

Indications

The vaccine is used for the simultaneous specific immunoprevention of measles, mumps and rubella in children and susceptible adults. After exposure to measles virus the vaccine can provide a certain protection against the disease provided it is applied within 72 hours at the latest. Vaccination with the vaccine is recommended, apart from common practice, in children with treated inactive or active T.B., with cystic fibrosis and chronic cardiac and pulmonary well compensated diseases.

Contraindications

- febrile diseases followed by convalescence (2 weeks),
- active untreated T.B.,
- therapy with ACTH, corticosteroids, radiation, alkylating agents or antimetabolites,
- proved serious disorder of immunity,
- leukaemia, lymphoma or other malignant neoplasma affecting medulla or lymphatic system,
- hypersensitivity to components of the vaccine e.g. neomycin, dog proteins (hairs),
- in the case of suspicion on an organic affection of the CNS, the vaccination is 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 in healthy children concurrently,
- 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.

Adverse effects

In the post-vaccination period a temperature reaction is most frequently observed in 20 % to 35 % of vaccinated subjects, exceptionally exceeding + 39 °C. Out of other general symptoms, exanthema, conjunctivitis, symptoms of the inflammation of the upper respiratory tract, fatigue, anorexia, swelling in the area of parotid gland, regional lymphadenopathy, arthralgia, exceptionally thrombocytopenia may occur. Most of the presented clinical symptoms appear between the 6th and 12th day after the vaccination and persist for 1 to 3 days, exceptionally longer.

Based on experience obtained up to now, no post-vaccination meningitis or meningo-encephalitis in the children vaccinated with the preparations containing the Czech attenuated strain of parotitis virus (PAVIVAC, MOPAVAC, TRIVIVAC) have been reported until now, i.e. their potential frequency is lower than 1 : 5,000,000.

Interactions

In order to avoid inactivating viruses contained in the vaccine:

- 1) by the transplacentally transferred maternal antibodies to child, the vaccination should not be carried out before reaching the first day of the 15th month of the age of the child.
- 2) by specific antibodies, the vaccine should not be administered 3 months after blood transfusion, the administration of plasma or human immunoglobulin. If the dose of immunoglobulin is higher than 10 mg/kg of body weight it is recommended to postpone the vaccination for 5 months.

TRIVIVAC should be administered 1 month before or 1 month after the administration of other live viral vaccines.

Routine administration of TRIVIVAC vaccine with other vaccines is not recommended because of a lack of data on concurrent administration with other antigens.

Skin reaction to tuberculin may transiently be suppressed by the measles component of vaccine. Therefore it is recommended to perform tuberculin test before the vaccination against measles or 6 weeks after the vaccination at the earliest.

Pregnancy and lactation

Pregnant women should not be vaccinated and in vaccinated women it is necessary to avoid pregnancy for a period of three months following the vaccination.

No information is available on the excretion of viruses contained in the vaccine into human breast milk. Caution is necessary in the administration of vaccine to breastfeeding women.

Dosage

The first dose of the vaccine should be administered to children starting from the 1st day of the 15th month of age. The

second dose should be applied earliest after 6 – 10 months following the first dose, or later according to the recommended vaccination schedule.

Mode of administration

The vaccine should be administered subcutaneously in a volume of 0.7 ml by disposable syringe. After disinfection of the site of puncture it is necessary each time to have the used disinfectant dried out before administration.

After the vaccination the child should remain for at least 30 minutes under medical surveillance.

Preparation of the solution

Immediately before vaccination perform the reconstitution of lyophilized vaccine with solvent for TRIVIVAC.

Inject the content of one ampoule of the solvent for TRIVIVAC (1.4 ml) into the ampoule containing two doses of the lyophilized vaccine or inject the content of one ampoule of the solvent for TRIVIVAC (0.7 ml) into the ampoule containing one dose of the lyophilized vaccine. Shake carefully the ampoule with lyophilized preparation to ensure thorough mixing of vaccine, which dissolves within one minute, producing a clear solution of yellow-orange to orange-red colour.

Note: Do not use ampoules containing prior to their opening, a red to violet coloured lyophilizate.

Caution

The liquid vaccine should be used not later than in 5 hours after reconstitution, provided that it was stored at +2 °C to +8 °C protected from light. Once opened ampoule must not be transferred or transported! In vaccinated women, the pregnancy should be ruled out for 3 months after vaccination.

In patients with proved significant hypersensitivity to dog proteins, to perform a skin test with the vaccine is recommended. No allergic reaction has been reported so far, which means that possible occurrence is lower than 1 : 10,000,000.

Storage

Store the ampoules with lyophilized vaccine and the ampoules with solvent for TRIVIVAC in a refrigerator (2 °C – 8 °C), keep the ampoules in the outer carton to protect the preparation from light. Do not freeze!

After reconstitution store the liquid vaccine in a refrigerator (2 °C – 8 °C), protected from light and administer within 5 hours following the reconstitution 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 the month. Keep out of the reach and sight of children!

Packing

TRIVIVAC 5 x 2 doses	+ 5 x 1,4 ml	of solvent for TRIVIVAC
TRIVIVAC 5 x 1 dose	+ 5 x 0,7 ml	of solvent for TRIVIVAC
TRIVIVAC 1 x 2 doses	+ 1 x 1,4 ml	of solvent for TRIVIVAC
TRIVIVAC 1 x 1 dose	+ 1 x 0,7 ml	of solvent for TRIVIVAC

Expiry date

Lyophilized vaccine: 18 months

Liquid vaccine after its reconstitution: maximally 5 hours

Solvent for TRIVIVAC: 2 years

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July 9, 2010

Marketing Authorisation Holder and Manufacturer

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