Merieux Inactivated Rabies Vaccine

PRODUCT INFORMATION

COMPOSITION

Inactivated Rabies Vaccine

DESCRIPTION

The vaccine is lyophilised, stabilised suspension of inactivated Wistar rabies virus strain PM/W1381503-3M, cultured on human diploid cells and inactivated by ß-propiolactone. These human diploid cells are a cell line derived from human embryonic lung tissue in the 1960s.

The dry vaccine is coloured off white but after reconstitution with the diluent supplied it turns a pinkish colour due to the presence of phenol red.

The potency of the reconstituted vaccine is not less than 2.5 IU, the WHO International Standard per dose (1 mL). Each vial contains, in addition, between 100 and 150 microgram of neomycin and up to 70 mg of human serum albumin.

The manufacture of this product includes exposure to bovine materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

PHARMACOLOGY

Following a single deep subcutaneous injection, an antibody response can be detected after a variable period of up to 7 days, in all subjects. Peak antibody levels are reached at about 30 days and then start to decline.

In order to maintain the antibody response multiple doses are necessary, in particular the booster doses on days 30 and 90 of the recommended immunisation schedule (see dosage and administration). Antibody titres of more than the minimum desirable value of 0.5 IU/mL are achieved in the plasma in almost all cases and usually maintained for 2 years. Reimmunisation at 2 years produces a boosted antibody response.

INDICATIONS

Post exposure immunisation against rabies. Pre-exposure immunisation in persons at special risk of contracting rabies.

CONTRAINDICATIONS

Pre-exposure immunisation in individuals sensitive to neomycin or other constituents of the vaccine.

WARNINGS

An antibody response may not occur in patients receiving corticosteroids or immunosuppressive therapy, or who have a previous immunodeficient state.

Antirabies human immunoglobulin depresses the antibody response to the Mérieux vaccine.

No more than the recommended dose of the antirabies immunoglobulin should, therefore, be used.

PRECAUTIONS

Corticosteroids should not be used during post exposure immunisation unless essential for the treatment of other conditions. Antibody levels should be monitored if corticosteroid treatment cannot be discontinued.

Do not administer intravenously or intradermally.

Adrenaline should be available for immediate use, should an anaphylactic reaction occur.

The full course of immunisation should be completed in order to obtain sustained antibody response.

Use in pregnancy - Category B2

The benefit clearly outweighs the risk for post exposure situations.

There is no convincing evidence of risk to the foetus from the immunisation of pregnant women using inactivated virus vaccines, bacterial vaccines or toxoids. Because of the potential consequence of inadequately treated rabies exposure, benefit to risk considerations may necessitate immunisation.

Use in Lactation

It is not known if the vaccine is secreted in human milk. Therefore, in pre-exposure cases, caution should be exercised when the vaccine is administered to a nursing woman. In post-exposure situations, benefit to risk considerations may necessitate immunisation.

ADVERSE REACTIONS

Redness, swelling or tenderness at the site of injection may occur during the first 48 hours. Itching and induration are other minor local reactions reported to occur at the injection site.

A mild fever, headache, nausea, abdominal pain, muscle aches and dizziness have been noted in approximately 20% of cases during the first 24 hours. Occasionally the febrile reaction may be severe.

The adverse reactions below have been reported subsequent to wide use of the vaccine, and in numerous cases, the causal relationship with the vaccine has not been established.

General reactions;
- shivering, malaise, asthenia
- paraesthesia
- arthralgia
- allergic skin reactions (urticaria, rash, itching, oedema)

In rarer cases;
- anaphylactic reactions
- serum sickness type reactions (following booster dose)

Exceptional cases of neuropathy have been reported.

In subjects with a history of allergy there may be an increased risk of adverse reactions and this possibility should be taken into account.

DOSAGE AND ADMINISTRATION

Use the 1 mL of solvent contained in the disposable syringe to reconstitute the freeze dried vaccine in the vial. Shake gently, then reaspirate the dissolved vaccine. The vaccine may be administered by deep subcutaneous injection, or by intramuscular injection, preferably into the deltoid region of the upper arm.

Prophylaxis

Primary Vaccination. Three injections of 1 mL on days 0, 7 and 28, by deep subcutaneous or intramuscular injection.

Booster. An injection of 1 mL after a year.

High antibody titres may be maintained by further boosters every 2 years, depending on the persisting exposure to the risk of infection.

Post exposure. Primary Vaccination. The vaccine treatment consists of deep subcutaneous or intramuscular injections on days 0, 3, 7 and 14, followed by booster doses on days 30 and 90.

In all cases of severe infection WHO recommends a treatment with 20 IU/kg antirabies human immunoglobulin on day 0. Overall management should follow WHO recommendations, see literature.

Post exposure therapy of previously immunised persons. Exposure of an immunised person (with demonstrated rabies antibodies) to rabies requires two booster doses at day 0 and 3. In other cases, a full course of immunisation should be administered.

Product is for single use in one patient only. Discard any residue.

OVERDOSAGE

Not documented.

PRESENTATION

Vial (powder for reconstitution), 1 mL solvent (distilled water): 1's.

STORAGE

Store refrigerated (2° to 8°C). Do not freeze. Use immediately after reconstituting the vaccine.

POISON SCHEDULE

S4 – Prescription Only Medicine

MANUFACTURER

Sanofi Pasteur SA
Lyon, France

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