TYPHIM Vi

POLYSACCHARIDE TYPHOID VACCINE

COMPOSITION

Each 0.5 ml immunizing dose contains:
– *Salmonella typhi* (Ty2 strain) polysaccharides ..... 0.025 mg
– Phenol and buffer solution containing sodium chloride, disodium phosphate, monosodium phosphate and water for injections.

PHARMACEUTICAL DOSAGE FORM

Injectable solution.
Prefilled syringe 0.5 ml.
Vial 20 doses (10 ml).

MARKETING AUTHORIZATION HOLDER

Aventis Pasteur SA
2, avenue Pont Pasteur, F-69007 Lyon

INDICATIONS

This medicinal product is a vaccine recommended for the prevention of typhoid fever in adults and children over 2 years.
TYPHIM Vi is intended for subjects travelling to endemic areas, migrants and health care workers.

CONTRAINDICATIONS

This medicinal product MUST NOT BE USED in the following cases:
– known allergy to any ingredient of the vaccine,
– in the event of fever, acute disease or progressive chronic disease, it is preferable to postpone the vaccination.

If there is any doubt, it is essential to consult your doctor or your pharmacist.

PRECAUTIONS FOR USE

This vaccine must not be injected by intravascular route: ensure that the needle does not enter a blood vessel.
This vaccine protects against the typhoid fever bacterium (*Salmonella typhi*), but not against related bacteria (*Salmonella* paratyphi A or B).
This vaccine is not indicated for children under 2 years of age since it is not sufficiently effective.

If there is any doubt, do not hesitate to consult your doctor or your pharmacist.
Keep out of the reach of children.

DRUG INTERACTIONS AND OTHER INTERACTIONS

In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor or to your pharmacist.

TYPHIM Vi can be administered with other vaccines (hepatitis A, yellow fever, diphtheria, tetanus, poliomyelitis, rabies, meningitis A + C and hepatitis B) during the same vaccination session.

PREGNANCY - BREAST FEEDING

During pregnancy, this medicinal product should only be used on medical advice.

As a general rule, during pregnancy and breast feeding, it is always recommended to ask your doctor's or pharmacist's advice before using a medicinal product.

DOSAGE AND ADMINISTRATION

RESERVED FOR ADULTS AND CHILDREN OVER 2 YEARS.
A single injection ensures protection.

Revaccination should be performed every 3 years if the subject continues to be exposed to the risk.
The vaccination schedule is the same for children and adults.

MODE AND ROUTE OF ADMINISTRATION

Intramuscular or subcutaneous route.

A successful extraction operation for one or more vaccine doses from a multidose vial depends essentially on the quality of the handling.

If the vaccine is an adsorbed vaccine, the vial must first of all be shaken gently, to avoid foaming, but sufficiently to obtain a homogenous mixture of the contents.

Then, using a sterile syringe fitted with a sterile needle, a single dose is withdrawn from the multidose vial, after disinfecting the outer surface of the vial stopper using a disinfectant.

For the subsequent dose(s), the same operation should be repeated.

Between the different withdrawal operations and, in any case, within not more than five minutes after the last dose withdrawn, the vial should be replaced in a refrigerator to keep the product at its normal storage temperature, i.e. between + 2°C and + 8°C (never place it in a freezer).

The manufacturer's legal liability covers the product up until its use.

The quality of the handling performed by the user to withdraw vaccine doses can affect the quality of a product packaged in a multidose vial. For this reason, the manufacturer cannot assume responsibility for the product over 24 hours after the first extraction operation unless the vial has been stored, in compliance with the manufacturer's recommendations, at a normal refrigerator temperature.

Thereafter, follow the W.H.O. recommendations which may be found in UNICEF or PAHO brochures.

SIDE EFFECTS

Like any active product, this medicinal product may in certain persons cause effects which are disturbing to a greater or lesser extent:
The effects reported after vaccination are generally moderate and short in duration. They mainly consist of local reactions at the injection point (pain, swelling, redness). Systemic reactions (fever, headaches, faintness, arthralgia, myalgia, nausea, abdominal pains) are reported more rarely.

In very rare cases, allergic-type reactions (pruritus, rash, urticaria) may be observed.

Report to your doctor or to your pharmacist any unwanted and disturbing effects which might not be mentioned in this leaflet.

STORAGE

Do not exceed the expiry date stated on the external packaging.

SPECIAL PRECAUTIONS FOR STORAGE

Store between + 2°C and + 8°C (in a refrigerator).
Do not freeze.

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Aventis Pasteur

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