

Vivotif Oral

Oral Typhoid Vaccine

Description

Vivotif Oral is an oral, live, attenuated typhoid vaccine for active immunization against typhoid and contains *Salmonella typhi* strain Ty21a Berna. Each enteric coated capsule contains not fewer than 2×10^9 viable organisms.

Actions

The attenuated Ty21a Berna strain is a mutant of *Salmonella typhi* which is deficient in the enzyme UDP-4-galactose epimerase. This results in the organisms being unable to effectively metabolize galactose. When grown in the presence of adequate amounts of galactose, the organism accumulates galactose-containing metabolites and ultimately undergoes spontaneous lysis. In the presence of a restricted supply of galactose the organism develops the smooth lipopolysaccharide coat believed to be necessary for immune response. In the intestine, where galactose is normally present, it is however unable to survive for long. The vaccine strain cannot be detected in the stools after 3 days following oral ingestion.

In one clinical study conducted in Egypt, in children above 6 years of age oral ingestion of the vaccine, as a solution preceded by a dose of sodium bicarbonate to reduce gastric activity (in order to reduce lysis of the organism in the stomach), provided approximately 95% protection against typhoid. In another study, conducted in Chile, enteric coated capsules provided approximately 70% protection. The duration of protection conferred by Vivotif Oral remains to be fully established. However, repeat vaccination is not considered necessary within 12 months after initial vaccination.

Indications

Vivotif Oral is indicated for active immunisation against typhoid in adults and children above 6 years of age. Effectiveness in children below 6 years of age is not known at present.

Contraindications

Primary and acquired immunodeficiency, including that from treatment with immunosuppressive and antimetabolic drugs: acute febrile illness: acute intestinal infection.

Warning

No data are currently available about the efficacy of Vivotif Oral in individuals with blood dyscrasias, leukaemia, lymphoma or any type of malignant neoplasm affecting the bone marrow or lymphatic system. These individuals may fail to develop protection because of their disturbed immune functions.

The capsules must be swallowed whole and not chewed because of the destruction of the organism by gastric acid.

The vaccine should not be administered concurrently with antibiotics or other drugs (eg. antimalarials, sulphonamides) which are active against salmonellae. The vaccine should be administered first and at least one week should elapse between the final dose of the vaccine and such drugs.

Pregnancy

Use in Pregnancy Category B2. Studies in animals are inadequate but available data show no evidence of an increased occurrence of foetal damage.

Adverse Reactions

These are infrequent and generally mild. In the reported trials the following adverse effects were noted - constipation, abdominal cramps, diarrhoea, nausea, vomiting, anorexia and fever.

Dosage and Administration

The Vivotif Oral capsule should be swallowed whole and must not be chewed. It should be taken one hour before a meal.

The dosage, irrespective of age, is one capsule on each of days 1, 3 and 5.

Storage and Shelf-life

Store between +2 and +8°C in a dry place and protected from light. Every package shows an expiry date: the product should not be used after this date.

Packaging

3 capsules in blister pack.

Overdosage

Should all three doses be accidentally taken at once, no serious consequences are to be expected and no counter measures need to be taken. However, an optimal immune response may not be elicited.

Medicine Classification

Prescription Medicine.

Distributed by:

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