Patient Group Direction (PGD) information for Vivotif

Vivotif®

Salmonella enterica serovar Typhi

The information contained in this document is a resource only and Emergent Biosolutions Inc can accept no responsibility for the following information if used as a pro forma PGD.

The information has been taken from the Vivotif Summary of Product Characteristics (July 2018) unless otherwise stated. Public Health England guidelines (Immunisation against infectious disease, Green Book, Chapter 33) should also be taken into consideration.

Some sections of this PGD information may vary according to local practices and legislation requires that PGDs be drawn up by the doctor, with whom the nurses who are to use it work, that a pharmacist be involved in the drawing up and that the appropriate health organisation ratifies it.

Therefore the PGD may vary according to local guidelines.

Prescribing information for Vivotif can be found on page 9.

Live vaccination for oral immunisation against typhoid fever

Name and address of practice / clinic / surgery		
Issue Number	Date	Expiry date

1) Clinical Situation

Clinical situation	Active immunisation against typhoid fever Current Department of Health recommendations are: • Travellers visiting typhoid-endemic areas whose planned activities put them at higher risk (please check the country information pages www.Nathnac.org and www.travax.nhs.uk) • Travellers to endemic areas (see above) with frequent and/or prolonged exposure to conditions where sanitation and food hygiene are likely to be poor • Laboratory personnel who may handle *S. typhi* in the course of their work

Inclusion criteria	Susceptible adults and children over 5 years of age who require active immunisation against typhoid fever.
Exclusion criteria	• To persons known to be hypersensitive to any component of the vaccine or the enteric-coated capsule (see Summary of Product Characteristics, section 6.1 (https://www.medicines.org.uk/emc/medicine/30294) • To persons with congenital or acquired immune deficiency (including patients receiving immunosuppressive or antimitotic drugs). • During an acute febrile illness or during an acute gastrointestinal illness. • Vaccination should be postponed until after recovery. • Infants under 5 years of age (see section on 'Use in children').
Cautions and warnings	Pregnancy and lactation (see section on 'Use in pregnancy / lactation')
Actions for excluded patients **Temporary exclusions**	Document reason in notes, refer to doctor, advise about transmission and preventative measures against contracting typhoid fever. For febrile or acute disease – rearrange date for administration of vaccine.
Action for those who refuse vaccination	Document in notes, refer to doctor, advise about transmission and preventative measures against contracting typhoid fever.
Arrangements for referral for medical advice	e.g. A doctor should always be present on the premises
Policies or guidelines **National**	1) Department of Health. Immunisation against Infectious Disease, 2006. Typhoid Chapter 33 https://www.gov.uk/government/publications/typhoid-the-green-book-chapter-33 2) Summary of Product Characteristics for Vivotif, live vaccination for immunisation against typhoid fever https://www.medicines.org.uk/emc/medicine/30294 3) National Travel Health Network & Centre (NaTHNaC) Typhoid Travel Health Information sheet (Oct 2015) http://travelhealthpro.org.uk/typhoid-and-paratyphoid/

2) Staff

Professional qualifications required	e.g. RGN
Additional training	e.g. Vaccine administration
Continuing training	
Facilities and equipment available	

3) Treatment

Name	Vivotif, Salmonella enterica serovar Typhi
Vaccine type	Oral vaccination
Legal classification	POM
Route of administration	Enteric capsules for oral administration
Prior to administration	Capsules should be taken 1 hour before a meal with cold or lukewarm water
Schedule	One capsule on days 1, 3 and 5. Protection against typhoid fever commences approximately 7-10 days after ingesting the third dose of vaccine. Revaccination: Vivotif Summary of product characteristics Revaccination is recommended at three years following the most recent vaccination for all individuals. Green Book, Chapter 33 In the case of travel from non-endemic area to an area where typhoid is endemic, a booster consisting of three doses is recommended every three years
Length of protection	Vivotif Summary of product characteristics Revaccination is recommended at three years following the most recent vaccination for all individuals. Revaccination comprises the ingestion of three capsules on Day 1, 3, and 5, as for the original vaccination schedule. Green Book, Chapter 33 In the case of travel from non-endemic area to an area where typhoid is endemic, a booster consisting of three doses is recommended every three years.
Onset of protection	Protection against typhoid fever commences approximately 7-10 days after ingesting the third dose of vaccine.
Storage	Store at 2-8°C. Protect from light
Patient (or parent / guardian as appropriate) advice given pre and post vaccination	e.g. Patient consent Patient information leaflet Advice on any expected reactions Advice on length of protection and the importance of scrupulous personal, food and water hygiene.

Written and oral advice and necessary follow-up	Always include the product's patient information leaflet. Medicines supplied for use under a PGD require that a label (that complies with the requirements of the Human Medicines Regulations 2012) be completed and affixed to the medicine: The standard labeling requirements for all dispensed items include: • the name and address of the person who supplies the medicinal product • the date of dispensing • the name of the person to whom the medicine is to be administered On supplying these medicines to the patient, the patient's name and date of supply along with the name and address of the person supplying must be completed on the label. During the consultation leading to administration of supply under PGD the patient must receive: • Advice on reactions and their management. • Advice on how the treatment is to be used if it is supplied rather than administered on site. During the course of treatment the patient must receive: • Advice specific to the condition being treated. • Advice on the expected outcome of treatment. • Advice that is specific to the service such as future access to the service • Advice on how the treatment will be followed up and by whom including when to make a future appointment. • Advice on where to seek further advice or a discussion of concerns.
Adverse reactions	The following adverse reactions were reported commonly (<1/10 but>1/100) in clinical studies: • Gastrointestinal disorders: abdominal pain, nausea, diarrhoea, vomiting • General disorders and administration site conditions: fever, Influenza-like illness • Nervous system disorders: headache • Skin and subcutaneous tissue disorders: rash The following additional adverse reactions have been reported very rarely (approximately <1/10,000) during post-marketing surveillance: • Skin reactions such as, dermatitis, exanthema, pruritus, urticaria • Anaphylaxis • Asthenia, malaise, tiredness, shivering • Paraesthesiae, dizzines • Arthralgia, myalgia.

Reporting procedures for adverse reactions	Patients should inform their doctor Information about adverse event reporting can be found at: www.mhra.gov.uk/yellowcard Adverse events should also be reported to Emergent Biosolutions at: pharmacovigilance@paxvax.com
Use in children	*Children under five years:* Safety and efficacy have not been established in children under five years of age.
Use in pregnancy / lactation	Animal reproduction studies have not been conducted with Vivotif. It is not known whether Vivotif can cause foetal harm when administered to pregnant women or can affect reproduction capacity. Vivotif should be given to a pregnant woman only if clearly needed. There are no data regarding administration of Vivotif to nursing mothers. It is not known if Vivotif is excreted in human milk.
Interaction with other medicinal products	As the growth of vaccine organisms may be inhibited by sulphonamides or antibiotics, vaccination should not commence within three days after completing treatment with any antibacterial agents. Also, it is preferable that antibacterial therapy should not commence within three days after the last dose of Vivotif. If malaria prophylaxis is also required, the fixed combination of atovaquone and proguanil can be given concomitantly with Vivotif. Doses of mefloquine and Vivotif should be separated by at least 12 hours. For other antimalarials, there should be an interval of at least three days between the last dose of Vivotif and the first dose of malaria prophylaxis. Vivotif may be administered concomitantly with the live attenuated vaccines yellow fever vaccine and oral polio vaccine.
Information recorded	Documentation should include: Patient details i.e. name, address, date of birth Administration details i.e. Dose, route of injection Vaccine details i.e. brand name, generic name, batch number, expiry date, indication for immunisation, date vaccine given. Health professional details: Name of clinic and who gave the vaccine Patient records: Personal record of vaccine details
Contact details	For ordering Vivotif contact Emergent Biosolutions at Polarspeed Email: PaxVax@polarspeed.com Direct Tel: 01525 216644 Fax: 01525 217516 For medical information: medicalinformation@paxvax.com 0800 088 5449
Data for patient group direction	Information based on Summary of Product Characteristics July 2018. For full product information, refer to most current Summary of Product Characteristics: https://www.medicines.org.uk/emc/medicine/30294

4. Management and Monitoring

Date of protocol	
Review date	
Protocol drawn up by: **Doctor** **Nurse** **Pharmacist**	
Advice received from	
Authorised / agreed by	Signed

This Patient Group Direction has been approved for use by:

	Name	Signature	Date
Chief Executive			
Senior CCG doctor			
Senior CCG pharmacist			
Senior CCG nurse			
Senior Partner (for GP employed nurses)			

The nurses named below are authorised to administer:
Vivotif, *Salmonella enterica* serovar Typhi, live vaccination for oral immunisation against typhoid fever.

Please sign if you agree to administer the above named vaccine in accordance with this patient group direction.

Name	Job title	Signed	Dated

Prescribing Information

Vivotif® (*Salmonella enterica serovar Typhi* Ty21a).
Please consult the full Summary of Product Characteristics, SmPC, before prescribing

Active ingredients: A single dose of Vivotif® contains at least 2 x 109 Salmonella Typhi Ty21a in a lyophilised form. Quantities expressed per capsule.

Pharmaceutical form: Enteric-coated capsule.

Therapeutic indications: For active oral immunisation against typhoid fever in children aged 5 years and over, adults and elderly. **Dosage and administration:** One dose of Vivotif is to be taken on days 1, 3 and 5, with cold or lukewarm water approximately one hour before meals. The protection becomes effective 7–10 days after ingestion of the third dose of vaccine. Re-vaccination is recommended at 3 years following the most recent vaccination.

Contraindications: Vivotif must not be administered: to persons known to be hypersensitive to any component of the vaccine or the enteric-coated capsule, to persons with congenital or acquired immune deficiency (including patients receiving immunosuppressive or antimitotic drugs), during an acute febrile illness or during an acute gastrointestinal illness. Vaccination should be postponed until after recovery. **Special warnings and precautions:** None known. **Side effects:** Abdominal pain, nausea, diarrhea, vomiting, fever, influenza-like illness, headache, rash. Consult SmPC in relation to very rare adverse reactions. **Pregnancy:** Vivotif should be given to a pregnant woman only if clearly needed.

Lactation: Vivotif should be administered during lactation only if clearly needed. **Interactions with other medicinal products and other forms of interaction:** The vaccination with Vivotif should be avoided during and for at least three days before and after antibiotic or sulphonamide treatment, due to possible inhibition of the growth of the vaccine organisms and potential attenuation of the immune response. If prophylaxis with antimalarials is planned, it is recommended to complete first the Vivotif vaccination and then start the malaria prophylaxis after an interval of at least three days between the last Vivotif dose and the start of malaria prophylaxis. Vivotif may be administered concomitantly with live attenuated parenteral vaccines and oral polio vaccine.

Special precautions for storage: Store at 2°C – 8°C. Protect from light.

Package quantities: 3 x 1 dose. Basic NHS cost: £14.77.

Legal category: POM.

Marketing authorisation number: 43552/0002

Marketing authorisation holder: PaxVax Ltd., 1 Victoria Square, Birmingham, B1 1BD

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to PaxVax on pharmacovigilance@paxvax.com

Date of last revision of Prescribing Information: July 2018