TYPHIM Vi
POLYSACCHARIDE TYPHOID VACCINE

COMPOSITION
Each 0.5 ml immunizing dose contains:
- Typhoid Vi polysaccharide ….……. 0.025 mg
- Phenol (preservative) ……...……. maximum 1.250 mg
- Isotonic buffer solution: sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, water for injection ……....q.s. 0.5 mL

PHARMACEUTICAL DOSAGE FORM
Solution for injection in prefilled syringe
Clear colorless solution
Ready-to-use, single-dose, 0.5 mL syringe.

THERAPEUTIC INDICATIONS
This vaccine is based on a constituent (capsular antigen) of the bacteria which causes typhoid fever for person two years of age or older.
Typhoid fever prevention becomes effective approximately 2 to 3 weeks after injection and protection lasts around 3 years.

POSOLOGY AND METHOD OF ADMINISTRATION
Posology
RESTRICTED TO ADULTS AND CHILDREN OVER 2 YEARS OF AGE.
A single injection (0,5 mL) by the intramuscular or subcutaneous route with protection lasts around 3 years.
If exposure to risk continues, revaccination will be performed every 3 years
Vaccination schedule is the same for children and for adults.
A successful extraction operation for one or more vaccine doses from a multidose vial depends essentially on the quality of the handling.

Method of administration
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 Then, using a sterile syringe fitted with a sterile needle, a single dose is withdrawn from the multidose vial, after disinfecting the outer surface of the vial stopper using a disinfectant.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Between the different withdrawal operations and, in any case, within not more than five minutes after the last dose withdrawn, the vial should be replaced in a refrigerator to keep the product at its normal storage temperature, i.e., between +2°C and +8°C (never place it in a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.

CONTRAINDICATIONS
The vaccination should not be administered, if the patient is known to be hypersensitive to one of the vaccine components or formaldehyde or to casein (which may be present as traces in each dose, owing to its use during the manufacturing process).
- Pregnancy: inform local doctor. See pregnancy section below.
- Children under 2 years old:
  - Typhoid fever is extremely rare in infants.

- This vaccine is not indicated in children under 2 years of age because of the risk of insufficient antibody response.

Vaccination should be postponed in case of acute febrile disease.
If there is any doubt, it is essential to consult your doctor or your pharmacist.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Postpone vaccination in the event of fever or severe infection.
As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available, in the event of a rare anaphylactic reaction following administration of the vaccine.
Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection, especially in adolescents. This may be accompanied by several neurological signs such as transient sight disorders, paresthesia and tonic-clonic limb movements during the recovery phase. It is important that procedures be in place to avoid any injury from faints.
Do not inject by the intravascular route.
This vaccine protects against the risks of infection by *Salmonella typhi* but not against *Salmonella paratyphi* A or B or non-typhoidal salmonella.
The immunogenicity of TYPHIM Vi may be reduced by immunosuppressive treatment or immunodeficiency. It is then recommended to wait until the end of the treatment or disease before vaccinating. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the immune response may be limited. Injection must be performed via the subcutaneous route in subjects with thrombocytopenia or bleeding disorders. If there is any doubt, do not hesitate to consult your doctor or your pharmacist. Keep out of the reach of children.

TYPHIM Vi contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially 'sodium-free'.
Traceability:
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORM OF INTERACTION
This vaccine can be associated with other common vaccines (hepatitis A, yellow fever, diphtheria, tetanus, poliomyelitis, rabies, meningitis A + C and hepatitis B) during the same vaccination session, using separate injection sites.

PREGNANCY AND LACTATION
Pregnancy
No reliable animal teratogenic data are available.
Currently, no sufficiently relevant clinical data are available to assess a potential teratogenic or foetotoxic effect of this vaccine when administered during pregnancy.
Therefore, the administration of the vaccine during pregnancy is not recommended. TYPHIM Vi should be given to pregnant women only if clearly needed and following an assessment of the risks and benefits.

Lactation
This vaccine can be used during lactation if the benefit out weights the risk.

EFFECT ON ABILITY TO DRIVE AND USE MACHINES
The effects on the ability to drive and use machines have not been studied.

UNDESIRABLE EFFECTS
a. Summary of the safety profile
More than 15,000 subjects received TYPHIM Vi (either in a single injection or as a second injection) in clinical studies.

The most common adverse reaction, in all age groups, was injection site pain. In adults from 18 years of age, myalgia and fatigue were the most frequently reported systemic reactions. In children and adolescents (from 2 to 17 years of age), myalgia and cephalalgia were the most frequently reported systemic reactions.
Most adverse reactions occurred within three days of vaccination. Most reactions resolved spontaneously within 1 to 3 days after onset.

b. Tabulated list of adverse reactions
The adverse reactions listed below come from clinical studies (pooled analysis) and worldwide post-marketing experience. The pooled analysis was performed on 6 recent studies sharing the same safety standard integrating data from 1532 subject (97 children and adolescents from 2 to 17 years of age and 1435 adults).

In each System Organ Class, the adverse events are ranked under headings of frequency, the most common reactions coming first, using the following convention:
Very common (≥1/10)
Common (≥1/100, <1/10)
Uncommon (≥1/1000, <1/100)
Rare (≥1/10 000, <1/1000)
Very rare (<1/10 000) including isolated cases.
Not known: cannot be estimated from available data.
The table below summarises the frequencies of adverse reactions recorded after any dose of TYPHIM Vi in children and adolescents from 2 to 17 years of age.

Adverse reactions	**Children and Adolescents 2-17 years (N= 97)**	**Adults ≥18 years (N=1435)**
	Frequency	**Frequency**
Immune system disorders		
Anaphylactic, anaphylactoid reactions, including shock	Not known*	
Serum sickness disease	Not known*	
Nervous system disorders		
Vasovagal syncope in response to injection	Not known*	
Cephalalgia	Very Common	Common
Respiratory, thoracic and mediastinal disorders		
Asthma	Not known*	
Gastrointestinal disorders		
Nausea	Not known*	
Vomiting	Not known*	
Diarrhoea	Not known*	
Abdominal pain	Not known*	
Skin and subcutaneous tissue disorders		
Allergic-like reactions such as pruritus, skin rash, urticaria	Not known*	
Musculoskeletal and connective tissue disorders		
Arthalgia	Not known*	
Myalgia	Very Common	Very Common
General disorders and administration site conditions		
Injection site pain	Very Common	

Injection site erythema	Very Common	Common
Injection site pruritus	-	Uncommon
Injection site swelling / Oedema / Induration	Very Common	Common
Malaise	Common	Very Common
Fever	Common	-
Fatigue / asthenia	Common	Very Common

*reported during post-marketing surveillance

The most frequently reported adverse reactions in children and adolescents (from 2 to 17 years of age) were injection site reactions: pain (52.6%), swelling / oedema / induration (16.5%) and erythema (14.4%).
In adults from 18 years of age, the most frequently reported adverse reactions were injection site pain (75.6%), myalgia (47.1%) and fatigue / asthenia (25.0%).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reaction via farmakovigilans@kalventis.com
and Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan.
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/.

PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: bacterial vaccines, ATC code: J07AP03.
This vaccine is prepared from purified Vi capsular polysaccharides of *Salmonella typhi*.
A double-blind, randomized, controlled efficacy clinical study was conducted in a highly endemic area in Nepal, in children and adults from 5 to 44 years. A total of 3,457 subjects received TYPHIM Vi. Compared with the control group (23 valence-pneumococcal polysaccharide vaccine), vaccine efficacy conferred by a single dose of vaccine TYPHIM Vi was 74% (CI 95%: 49; 87) against blood culture-confirmed cases of typhoid fever throughout the 20 months of active surveillance.
Seroconversion rate (defined as 4-fold rise of anti-Vi antibody levels) was collected in 19 clinical trials. These trials were conducted in endemic and non-endemic areas in adults and children from 2 years of age representing a total of 2,137 evaluable subjects. In the adult population, the seroconversion rate ranged from 62.5% to 100% four weeks after a single injection, with similar magnitude of anti-Vi immune response in non-endemic areas compared to endemic areas.
Anti-Vi antibody persistence depends on endemicity, with a trend for better persistence in endemic areas (documented up to 10 years in 83 children at levels equal or above 1 µg/mL considered as a serological indicator of protection against typhoid fever). In non-endemic areas, anti-Vi antibodies persist for 2 to 3 years with rates above 1 µg/mL around 41% after two years and 35.6% after 3 years of vaccination with TYPHIM Vi. Revaccination should be carried out with a maximum interval of 3 years if the subject is still exposed to the risk.

Paediatric population
In a double-blind, randomized, controlled efficacy clinical study conducted in a highly endemic area in South Africa, a total of 5,692 subjects from 5 to 15 years of age received TYPHIM Vi. Compared with the control group (meningococcal polysaccharide vaccine of groups A and C), vaccine efficacy conferred by a single dose of vaccine TYPHIM Vi was 55% (CI 95% : 30 ; 71) against blood culture-confirmed cases of typhoid fever during a 3-year follow-up.

Immunogenicity was assessed in both endemic and non-endemic areas in paediatric population aged from 2 to 17 years. In 9 clinical studies including 733 evaluable children, four weeks after a single injection of TYPHIM Vi, the seroconversion rate ranged from 67% to 100%, with a magnitude of anti-Vi immune response similar to that documented in adult.

SHELF LIFE
3 years.

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

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

PACKAGES:
Pre-filled Syringe @0.5 mL Reg. no. DKI2059703743A1

HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

DNA babi tidak terdeteksi pada produk akhir

Manufactured by:
Sanofi Winthrop Industrie, Marcy L'Etoile - France

Registered by:
PT Kalventis Sinergi Farma, Jakarta - Indonesia

TYPHIM Vi

POLYSACCHARIDE TYPHOID VACCINE

Larutan injeksi dalam *syringe*

Bacalah seluruh leaflet ini dengan seksama sebelum Anda divaksinasi karena isi dalam selebaran ini mengandung informasi yang penting bagi Anda.

- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Vaksin ini telah diresepkan secara khusus untuk Anda. Jangan berikan ke orang lain.
- Jika salah satu efek samping menjadi semakin serius atau jika Anda menyadari efek samping apapun yang tidak tercantum dalam leaflet ini, hubungi dokter atau apoteker Anda.

Apa saja informasi dalam leaflet ini:

1. APA ITU TYPHIM Vi DAN APA KEGUNAANNYA

TYPHIM Vi merupakan vaksin yang mengandung antigen kapsular dari bakteri yang dapat menyebabkan demam tifoid dan diberikan pada pasien dengan usia 2 tahun keatas.

Pencegahan demam tifoid berlangsung efektif sekitar 2 atau 3 minggu setelah penyuntikan.

Vaksin ini dapat memberikan perlindungan minimal selama 3 tahun.

2. INFORMASI YANG PERLU ANDA KETAHUI SEBELUM MENGGUNAKAN TYPHIM Vi

Jangan gunakan TYPHIM Vi

- Jika Anda alergi dengan bahan aktif, atau dengan salah satu komponen lain dari TYPHIM Vi, atau dengan formaldehid atau dengan kasein.
- Jika Anda sedang hamil, maka segera konsultasikan ke dokter Anda. Lihat bagian kehamilan.
- Anak usia di bawah 2 tahun. Demam tifoid jarang ditemukan pada anak bayi baru lahir. Vaksin ini tidak ditujukan untuk anak usia di bawah 2 tahun karena risiko respon imun yang tidak mencukupi.
- Vaksinasi sebaiknya ditunda apabila denyut jantung tidak beraturan (fibrilasi akut).

Perhatian khusus menggunakan TYPHIM Vi

- Jika Anda sedang panas tinggi, maka vaksinasi harus ditunda sampai Anda sembuh
- Petugas dan tindakan darurat harus selalu tersedia apabila terjadi reaksi anafilaksis setelah pemberian vaksin
- Pingsan dapat terjadi (kebanyakan pada remaja) setelah atau bahkan sebelum penyuntikkan. Sehingga, informasikan kepada dokter atau perawat jika Anda pernah mengalami pingsan pada penyuntikkan sebelumnya

DISETUJUI OLEH BPOM: 26 AGUSTUS 2025

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- Tidak dapat diberikan melalui injeksi intravaskular
- Vaksin ini melindungi dari bakteri demam tifoid (*Salmonella typhi*), namun tidak melindungi dari bakteri yang lain (*Salmonella paratyphi* A atau B) atau salmonella non-tifoid
- Pengobatan immunosupresif atau immunodefisiensi dapat menurunkan imunogenisitas Typhim Vi. Vaksinasi dapat dilakukan setelah proses pengobatan selesai. Vaksinasi untuk pasien HIV (*Human Immunodeficiency Virus*) dapat direkomendasikan meskipun respon imun tubuh terbatas
- Jika Anda menderita hemophilia atau mudah mengalami memar atau berdarah penyuntikkan dapat diberikan melalui area dibawah kulit (subkutan).

Anak-anak
Vaksin ini tidak diindikasikan pada anak berusia di bawah 2 tahun karena tidak cukup efektif.

TYPHIM Vi mengandung kurang dari 1 mmol natrium (23 mg) per dosis, artinya pada dasarnya "bebas natrium".
Ketertelusuran:
Untuk meningkatkan ketertelusuran produk obat biologis, nama dan nomor bets produk yang diberikan hendaklah dicatat dengan jelas.

Interaksi dengan obat-obatan lain
- TYPHIM Vi dapat dikaitkan dengan vaksin umum lainnya (hepatitis A, *yellow fever,* difteri, tetanus, poiliomielitis, rabies, meningitis A + C, dan hepatitis B) pada waktu yang sama dengan tempat suntikkan yang berbeda.

Kehamilan dan Menyusui
<u>Kehamilan</u>
Belum tersedia studi pada hewan
Saat ini, belum tersedia data klinis terkait potensi efek teratogenik atau foetotoksik pada TYPHIM Vi saat digunakan selama kehamilan
Oleh karena itu, pemberian vaksin selama kehamilan tidak direkomendasikan. TYPHIM Vi sebaiknya diberikan pada wanita hamil hanya jika jelas diperlukan dan dengan mengikuti penilaian risiko dan manfaat.

<u>Menyusui</u>
TYPHIM Vi dapat diberikan selama menyusui jika manfaat lebih besar daripada risikonya.

Mengemudi dan Mengoperasikan Mesin:
Belum ada studi lanjutan mengenai efek kepada kemampuan dalam mengemudi dan mengoperasikan mesin.

3. ATURAN PAKAI TYPHIM Vi

Dosis:
HANYA UNTUK DEWASA DAN ANAK USIA 2 TAHUN KE ATAS
TYPHIM Vi diberikan dengan dosis tunggal (0.5 mL) dengan proteksi minimum 3 tahun setelah

pemberian.
Jika resiko paparan berlanjut, vaksinasi ulang akan dilakukan setiap 3 tahun
Jadwal vaksinasi sama antara dewasa dan anak-anak

Cara Pemberian:
TYPHIM Vi diberikan melalui injeksi subkutan dalam atau intramuskular oleh tenaga kesehatan professional. Setelah digunakan, vial harus disimpan di kulkas pada suhu +2ºC sampai +8ºC.

4. EFEK SAMPING YANG MUNGKIN DAPAT TERJADI

Pada setiap kelas sistem organ, reaksi efek samping diurutkan berdasarkan frekuensinya, dari reaksi yang sangat umum terjadi, dengan menggunakan beberapa konvensi berikut:
Sangat umum (≥1/10)
Umum (≥1/100, <1/10)
Tidak umum (≥1/1000, <1/100)
Jarang terjadi (≥1/10 000, <1/1000)
Sangat jarang terjadi (<1/10 000)
Tidak diketahui: tidak dapat diperkirakan dari data yang tersedia.
Tabel di bawah ini merangkum frekuensi reaksi merugikan yang dicatat setelah pemberian dosis TYPHIM Vi pada anak-anak dan remaja dari usia 2 hingga 17 tahun.

Efek samping	**Anak-anak dan remaja 2-17 years (N=97)**	**Individu Dewasa** ≥ 18 tahun
	Frekuensi	**Frekuensi**
Gangguan sistem kekebalan tubuh		
Anafilaktik, reaksi anafilaktoid, termasuk syok	Tidak diketahui*	
Penyakit serum	Tidak diketahui*	
Gangguan sistem saraf		
Sinkop vasovagal sebagai respon terhadap injeksi	Tidak diketahui*	
Sakit kepala	Sangat umum	Umum
Gangguan pernapasan, toraks, mediastinum		
Asma	Tidak diketahui*	
Gangguan pencernaan		
Mual	Tidak diketahui*	
Muntah	Tidak diketahui*	
Diare	Tidak diketahui*	
Nyeri perut	Tidak diketahui*	
Gangguan kulit dan jaringan subkutan		
Reaksi menyerupai alergi seperti gatal (pruritus), ruam kulit, urtikaria	Tidak diketahui*	
Gangguan musculoskeletal dan jaringan penghubung		

Nyeri sendi	Tidak diketahui*	
Nyeri otot	Sangat umum	Sangat umum
Gangguan umum dan kondisi tertentu		
Nyeri di tempat suntikan	Sangat umum	
Kemerahan di tempat suntikan	Sangat umum	Umum
Gatal (pruritus) di tempat suntikan	-	Tidak umum
Pembengkakan / edema / pengerasan di tempat suntikan	Sangat umum	Umum
Rasa tidak enak badan	Umum	Sangat umum
Demam	Umum	-
Kelelahan / kelemahan yang tidak biasa	Umum	Sangat umum

** dilaporkan selama pengawasan pasca-pemasaran*

Reaksi yang paling sering dilaporkan pada anak-anak dan remaja (usia 2 hingga 17 tahun) adalah reaksi di tempat suntikan: nyeri (52,6%), pembengkakan / edema / pengerasan (16,5%) dan kemerahan (14,4%)
Pada orang dewasa dari usia 18 tahun, reaksi yang paling sering dilaporkan adalah nyeri di tempat suntikan (75,6%), nyeri otot (47,1%) dan kelelahan / kelemahan yang tidak biasa (25,0%).

Pelaporan efek samping
Jika Anda atau anak Anda mendapatkan efek samping, bicarakanlah dengan dokter, apoteker atau perawat Anda. Termasuk kemungkinan efek samping yang tidak tercantum dalam brosur ini.
Anda juga dapat melaporkan efek samping secara langsung ke Industri Farmasi dengan kontak berikut farmakovigilans@kalventis.com.
Dengan melaporkan efek samping Anda dapat membantu memberikan informasi tentang keamanan obat ini.

5. CARA MENYIMPAN TYPHIM Vi

Tanggal kadaluarsa produk selama 3 tahun
Produk harus disimpan pada suhu 2 ºC sampai 8 ºC (di kulkas). Vaksin tidak boleh dibekukan. Jangan menggunakan Typhim Vi setelah masa tanggal kadaluarsa yang tercantum pada dus

6. INFORMASI LEBIH LANJUT

Apa yang terkandung dalam Typhim Vi

Bahan aktif: *Thypoid Vi polysaccharide* ..... 25 mcg
tiap 0.5 mL dosis

Komponen lain: fenol dan larutan penyangga isotonik yang berisi natrium klorida, dinatrium fosfat dihidrat, natrium dihidrogen fofat dihidrat dan air untuk injeksi secukupnya 0.5 mL.

Seperti apa bentuk TYPHIM Vi dan isi kemasannya

TYPHIM Vi tersedia dalam bentuk larutan untuk injeksi (0.5 mL dalam *prefilled syringe* dengan atau

tanpa jarum). Dus berisi 1 syringe
Larutan TYPHIM Vi berupa larutan jernih dan tidak berwarna.

HARUS DENGAN RESEP DOKTER

KEMASAN:
Dus, *prefilled syringe* @ 0.5 mL
Reg. No. DKI2059703743A1

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

DNA babi tidak terdeteksi pada produk akhir

Diproduksi oleh: Sanofi Winthrop Industrie, Marcy L'Etoile – France

Didaftarkan oleh: PT Kalventis Sinergi Farma, Jakarta - Indonesia