PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

TYPHIM Vi solution for injection

Vi capsular polysaccharide typhoid fever vaccine

Sugar free.

Read all of this leaflet carefully before getting vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This vaccine is not for self-administration and should be administered by a healthcare professional.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- Make sure that the whole immunisation schedule has been completed.

What is in this leaflet

1. What TYPHIM Vi is and what it is used for

TYPHIM Vi is a vaccine indicated in the prevention of typhoid fever in adults and in children over 2 years of age.

TYPHIM Vi is especially indicated for inhabitants of endemic zones, travellers to endemic areas,

migrants, healthcare professionals, catering and food industry professionals, and military personnel.

2. What you need to know before you use TYPHIM Vi

Do not use TYPHIM Vi if you or your child:

- Are/is allergic (hypersensitive) to TYPHIM Vi or to any ingredients of the vaccine (see section 6 for a list of ingredients).
- Suffer/s from fever, an acute disease, or a progressive chronic disease (in which case administration of the vaccine should be postponed).

Warnings and precautions:

- This vaccine must not be injected via the intravascular route: make sure the needle does not penetrate a blood vessel.
- This vaccine protects against typhoid fever bacterium (*Salmonella typhi*), but not against related bacteria (*Salmonella paratyphi A* or *B*).
- As each dose contains formaldehyde and casein (milk protein), caution should be exercised when the vaccine is administered to subjects with hypersensitivity (undesirable reactions produced by the normal immune system, including allergies) to these ingredients.
- Immune suppressive treatments or a state of immune deficiency may lead to diminished immune response to the vaccine. It is recommended to postpone the vaccination until the end of disease treatment. Vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response is limited.
- This vaccine is not indicated in children below 2 years of age because efficacy is not adequate in this age group.
- As with other polysaccharide vaccines, the antibody response may be inadequate in children under 2 years of age.
- Vaccination should occur at least 2 weeks prior to potential exposure to infection with *Salmonella typhi*.
- Fainting may occur following, or even before any vaccination as an emotional and mental

response to needle injection. Inform your healthcare professional if you have a fear of needles.

Other medicines and TYPHIM Vi:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

TYPHIM Vi may be given together with other vaccines (hepatitis A, yellow fever, diphtheria, tetanus, poliomyelitis, rabies, meningitis A + C and hepatitis B) during the same vaccination session using different injection sites.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving TYPHIM Vi. They will decide whether or not to delay the vaccination.

3. How to receive TYPHIM Vi

Posology

RESTRICTED TO ADULTS AND CHILDREN OVER TWO YEARS OF AGE.

A single injection ensures protection.

Revaccination should be performed every 3 years if the risk of exposure continues.

The vaccination schedule is the same for children and for adults.

Method and route of administration:

Intramuscular or subcutaneous routes.

Any unused product or waste material should be disposed of in accordance with local requirements.

If you receive more TYPHIM Vi than you should:

Cases of over dosage are not known with TYPHIM Vi.

4. Possible side effects

TYPHIM Vi can have side effects.

Not all side effects reported for TYPHIM Vi are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving TYPHIM Vi, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving TYPHIM Vi and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TYPHIM Vi. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Asthma (difficulty breathing, wheezing and/or coughing)
- Serum sickness type reactions (rash, itching, joint pain, fever, swelling of the lymph nodes)

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- myalgia (muscle pain)
- injection site pain, injection site erythema (redness of the skin), injection site oedema (fluid retention), injection site induration (hardening) and injection site swelling
- malaise (general discomfort)
- fever

- fatigue (tiredness), asthenia (weakness)

Less frequent side effects:

- injection site pruritus (itchiness)

Other side effects where the frequency cannot be determined:

- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- abdominal pain
- allergic skin reactions such as rash, pruritus (itching), urticaria (hives)
- arthralgia (joint pain)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256-3700 (tel), or
- SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of TYPHIM Vi.

5. How to store TYPHIM Vi

- Store all medicines out of reach of children.
- Store in a refrigerator (between +2 °C and +8 °C).
- Protect from light.
- Shake well before use.

- Do not use after the expiry date stated on the label and box.
- DO NOT FREEZE. DISCARD IF FROZEN.

6. Contents of the pack and other information

What TYPHIM Vi contains:

Polysaccharides of *Salmonella typhi* (Ty2 strain) (25 micrograms for one dose of 0,5 mL).

The other ingredients are phenol and a buffer solution containing sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate and water for injection.

The syringe contains the diluent with:

sodium chloride

water for injections.

What TYPHIM Vi looks like and contents of the pack:

TYPHIM Vi is a clear, colourless liquid vaccine.

TYPHIM Vi is available in 1 x single dose pre-filled syringe (type 1 neutral glass) with a black elastomer plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl) and black needle shield covering a 25-gauge needle.

Holder of the certificate of registration:

sanofi-aventis south africa (pty) ltd

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South Africa

Tel. no.: 011 256 3700

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