SANOFI PASTEUR

410 Thames Valley Park Drive
Reading,
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RG6 1PT
United Kingdom

12th February 2020

Dear Healthcare Professional,

Supply of Standard Export pack of Typhim Vi solution for injection PL 46602/0008 - Lot R2A244M, Expiry 30/04/2021 – Single Packs

Due to higher demand for our Typhoid polysaccharide vaccine (Typhim Vi) than anticipated, we have obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply the above batch of stock which is supplied in Standard Export packaging. These packs are labelled with Lot number R2A244M with an expiry date of 30/04/2021.

The product supplied in Standard Export packaging is identical to the product authorised for use in the UK apart from some minor differences. The product in Standard Export packaging is supplied as a prefilled syringe with attached needle (the usual presentation supplied in the UK is a prefilled syringe without needle). In addition, there are a number of differences in the packaging as follows:

- There are three languages on each component of the Standard export pack: carton, label and leaflet (English, French and Spanish).
- Both the UK and Standard Export packs use the same colour combination on the carton (blue & green on a white background) but the design is different.
- The Standard Export pack carton is larger in size than the UK single pack for Typhim Vi.

Certain pieces of guidance on administration, patient aftercare and storage of the vaccine which are included on the carton and/or in the package leaflet of the UK licensed product are missing from the standard export pack and this information is listed below:

- The syringe should be shaken immediately prior to administration of the vaccine.
- The syringe should be stored in the outer carton in order to protect from light.
- The vaccine should be administered at least two weeks before protection from typhoid fever is required.
- Incidences of tiredness have been reported following vaccination; therefore care should be taken when driving or using machinery after vaccination.
- Side effects can be reported directly to the MHRA via the Yellow Card scheme (see below).
- Serum sickness disease has been reported following administration of Typhim Vi but the frequency is not known.
- The legal category of the vaccine is Prescription Only Medicine (POM).

Full information on the vaccine can be found in the approved Summary of Product Characteristics published on the Electronic Medicines Compendium website (www.medicines.org.uk/emc).

Please explain to patients being administered with stock in Standard Export packaging that these packs are approved for use in the UK.

If you have any questions, please contact the Sanofi Pasteur Medical Information Department on 0845 372 7101.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store. When reporting a suspected ADR to a vaccine, please provide the brand name (or product licence number and manufacturer), and the specific batch-number.
Adverse events should also be reported to Sanofi Pasteur telephone number 0800 0902314.

Yours faithfully,

Dr Ian GRAY
Head of Medical
Sanofi Pasteur UK/IRE