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23/March/2021

Priorix Vaccine

(Live trivalent attenuated measles, mumps and rubella vaccine)

Priorix vaccine will be supplied as a single-dose in a Singapore pack.

Dear Healthcare Professional,

This communication is intended for Healthcare Professionals who administer the *Priorix* vaccine to patients.

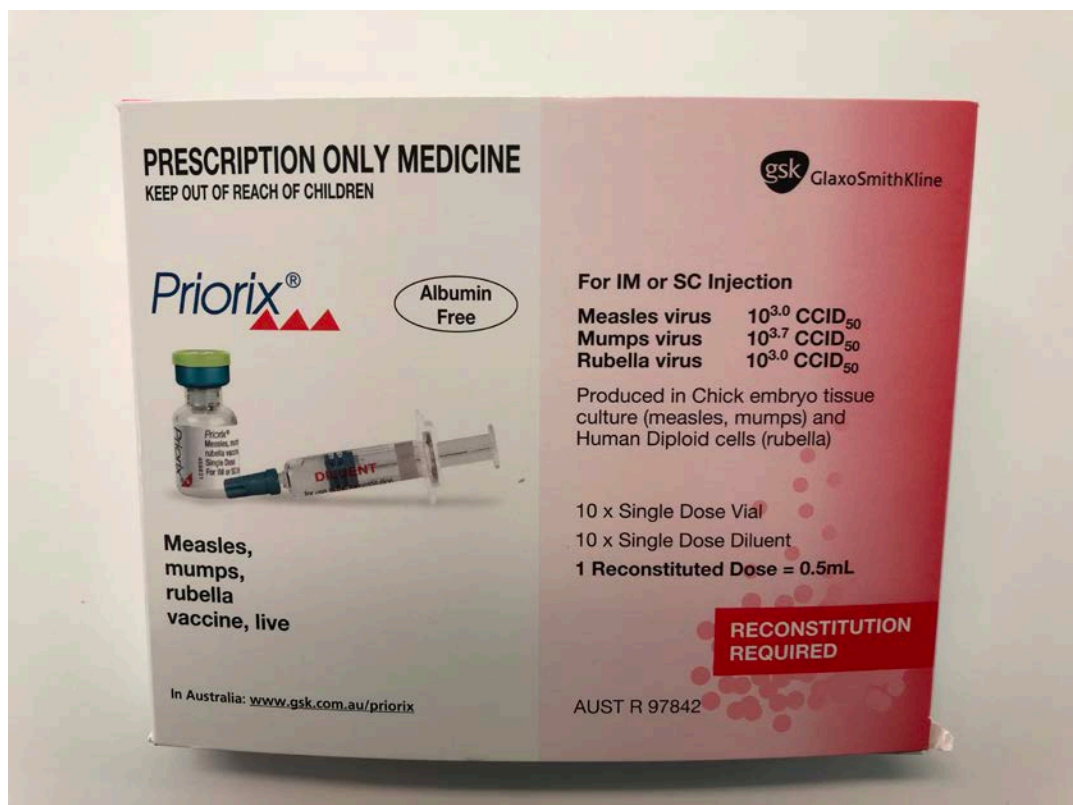
Summary

GSK is providing additional supply of *Priorix* vaccine with a Singapore pack and leaflet to the New Zealand market, upon request from PHARMAC. The **vaccine is the same** in formulation and presentation as what is routinely supplied to NZ.

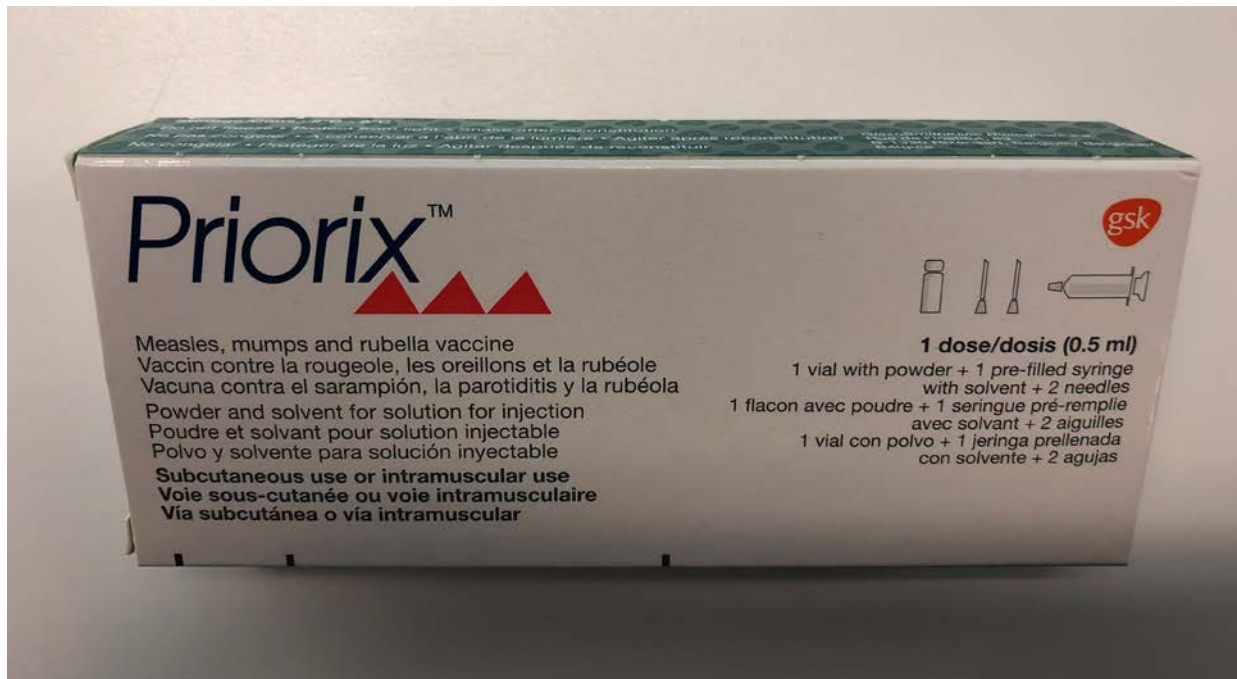
Batch Number: A69CF005A Expiry Date: 05/2021
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Packaging changes

The *Priorix* vaccine with a Singapore pack is supplied as a single dose pack and comes with 2x 25G 5/8 needles. Currently *Priorix* comes in a 10 dose pack, with no needles.



New Zealand Packaging



Singapore Packaging

Leaflet changes

There are some minor differences between the leaflet supplied in the *Priorix* with the Singapore pack and the New Zealand Data Sheet. Please note the following:

Indication

The Singapore *Priorix* leaflet does not state in the indication section “from 12 months of age” as per the New Zealand *Priorix* Data Sheet. However, it does include relevant information on the minimum age to vaccinate in the “Warnings and Precautions” section which is aligned with the New Zealand Data Sheet.

Method of Administration

The Singapore leaflet does not include the statement “*Priorix must not be administered intravascularly*” in the Method of Administration section. However, this is included in the Warnings and Precautions section in the Singapore leaflet which is aligned with the New Zealand *Priorix* Data Sheet.

Pharmaceutical particulars – special precautions for storage

The Singapore leaflet includes the following additional information “*The solvent can be stored in the refrigerator or at ambient temperature*”. This information is aligned with the NZ Therapeutic Product Database Report.

Instructions for Use/Handling

The Singapore leaflet includes additional information about the Multidose (2 dose) presentation registered in Singapore, which is not registered in New Zealand.

Priorix is a prescription medicine. The New Zealand Data Sheet and Consumer Medicine Information for *Priorix* may be accessed at: www.medsafe.govt.nz

For further information about *Priorix*, please contact GSK Pharmaceuticals Medical Information Department on 0800 808 500.

Please report any suspected adverse events to the Centre for Adverse Reactions Monitoring (CARM) online at <https://nzphvc.otago.ac.nz/reporting> or by email to carmnz@otago.ac.nz

Yours Sincerely,

Melissa Bentley
Vaccines Medical Affairs Manager, GSK NZ

Priorix (Live trivalent attenuated measles, mumps and rubella vaccine) is a prescription medicine available as an injection. This vaccine should be administered by subcutaneous injection, although can be given by intramuscular injection. Each 0.5 mL dose of the reconstituted vaccine contains not less than 103.0 CCID50 of the Schwarz measles, not less than 103.7 CCID50 of the RIT 4385 mumps (derived from Jeryl Lynn strain), and not less than 103.0 CCID50 of the Wistar RA 27/3 rubella virus strains. *Priorix* is indicated for active immunisation against measles, mumps and rubella. *Priorix* is funded on the National Immunisation Schedule at 15 months and 4 years of age. Contraindications: known systemic hypersensitivity to neomycin or to any other component of the vaccine. Do not administer to subjects with impaired immune function or pregnant women. Pregnancy should be avoided for 1 month after vaccination. Precautions: do not administer intravenously; ensure medical treatment is readily available in case of rare anaphylactic reaction following administration. May contain traces of egg protein. Individuals who have experienced anaphylaxis after egg ingestion should be vaccinated with extreme caution. Postpone administration in subjects suffering from acute severe febrile illness; presence of a minor infection is not a contraindication. Common side effects include upper respiratory tract infections, rash and local reactions such as pain, redness, and swelling at the injection site. Very rarely reported reactions include allergic reactions including anaphylactoid reactions. In rare cases a mumps-like condition and measles-like syndrome has been reported. Before prescribing *Priorix*, please review the full Data Sheet at www.medsafe.govt.nz. *Priorix* is a registered trade mark of the GlaxoSmithKline group of companies. Marketed by GlaxoSmithKline NZ Limited, Auckland. DA2119MB-PM-NZ-MSX-LTR-21MAR0001.

Adverse events involving GlaxoSmithKline products should be reported to GSK Medical Information on 0800 808 500.

GlaxoSmithKline NZ Limited
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