Government of **Western Australia**
Department of **Health**

Dear WA Immunisation Provider,

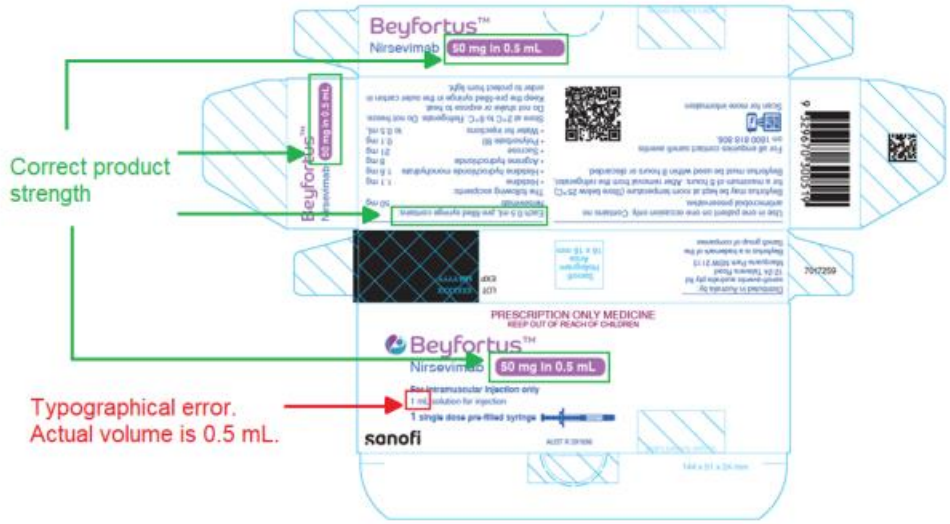
Re: Notification of Typographical Error on Carton for BEYFORTUS (nirsevimab) 50 mg in 0.5 mL solution for injection pre-filled syringe (AUST R 397898) – Batch 2043111

I am writing to inform you that on 11 April 2024 Sanofi advised the WA Department of Health of a typographical error on the carton of the single dose pre-filled syringe for the 50 mg in 0.5 mL presentation of BEYFORTUS (AUST R 397898)/nirsevimab.

The error has no impact on the quality or strength of the product, and it remains suitable for use.

The typographical error mistakenly reads “1 mL” instead of “0.5mL” in one of five locations where the strength is listed on the carton, as shown below (Figure 1).

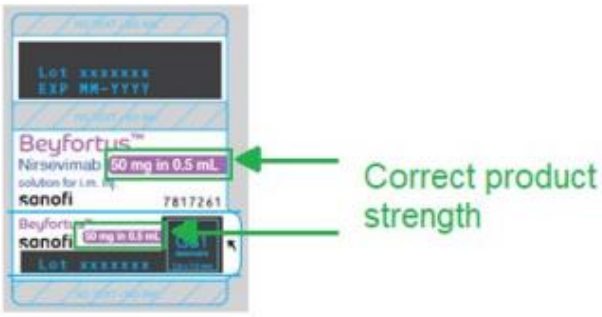
Figure 1: Carton Label (50 mg in 0.5 mL)



Please be advised that:

- The correct product strength (50mg in 0.5mL) is still stated on all faces of the carton.
- The correct product strength (50mg in 0.5mL) is stated on the syringe label (Figure 2).

Figure 2: Syringe Label (50 mg in 0.5 mL)



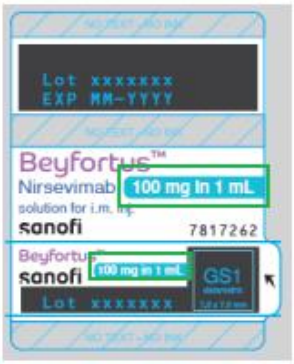
- The syringe contains 0.5mL of solution for injection.

- The contents of the entire syringe should be administered to deliver a single 50 mg dose.

There are no errors on the carton for the 100 mg in 1 mL Beyfortus presentation (AUST R 397899) which correctly states in all locations on the carton and the syringe label (Figures 3 and 4) that the total volume of the single dose pre-filled syringe is 1 mL.

Figure 3: Carton Label (100 mg in 1 mL)

Figure 4: Syringe Label (100 mg in 1 mL)



The two product presentations are also clearly differentiated by colour with the 50mg strength being purple and the 100mg strength in light blue.

We apologise for any inconvenience.

Sincerely,

Dr Paul Effler, MD, MPH, FAFPHM
Senior Medical Advisor
Communicable Disease Control Directorate

12 April 2024