11 April 2024

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

Dear Healthcare Professional,

Sanofi is writing to advise you 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). The **total volume** is stated as **1 mL** instead of **0.5mL** on the front carton face as shown below.

- Product strength (50mg in 0.5mL) is correctly stated on all faces of the carton.
- Product strength (50mg in 0.5mL) is correctly stated on the syringe label.
- The syringe contains 0.5mL of solution for injection.
- The contents of the entire syringe should be administered to deliver a single dose of 50 mg.

The error has no impact on product quality and BEYFORTUS (nirsevimab) 50 mg in 0.5 mL solution for injection is suitable use in ongoing immunisation programs.

The Australian Product information for BEYFORTUS nirsevimab (available at https://www.ebs.tga.gov.au) states that the entire contents of the 50mg in 0.5mL syringe must be administered to administer the 50mg dose.

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

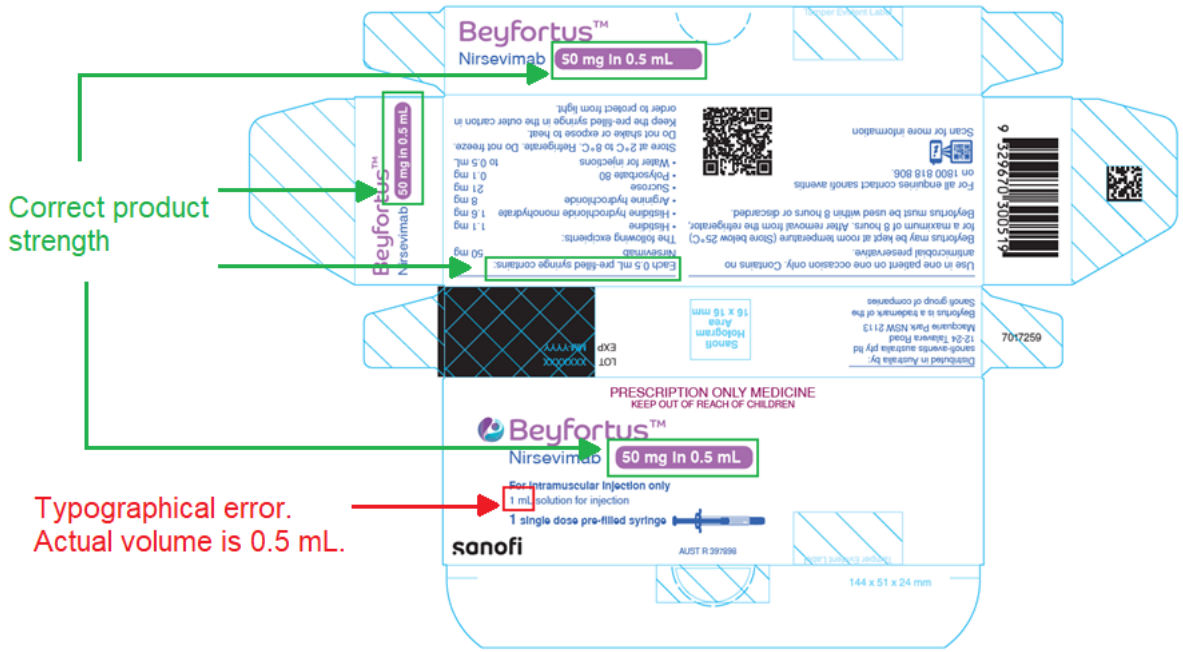

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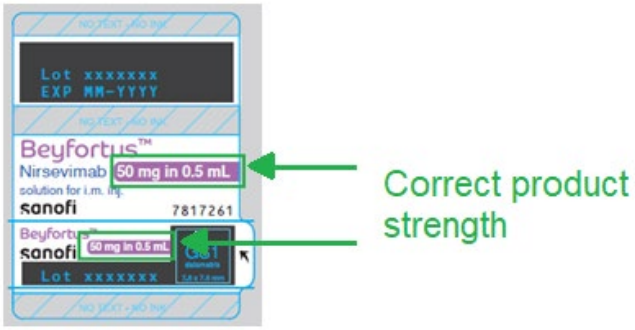
Figure 2: Syringe Label (50 mg in 0.5 mL)



There is no error on the carton for the 100 mg in 1 mL Beyfortus presentation (AUST R 397899) which correctly states the **total volume** of the single dose pre-filled syringe as 1 **mL**.

- The two product presentations are clearly differentiated **by colour and product strength on the carton and label** (see Figures 1-4):
  - 50mg in 0.5mL strength is shown in purple highlight
  - 100mg in 1 mL strength is show in blue highlight

Adverse Event Reporting
As a new approved product in Australia, Beyfortus is subject to additional monitoring that will allow quick identification of new safety information. Any adverse events which are experienced with BEYFORTUS nirsevimab 50 mg in 0.5 mL solution for injection pre-filled syringe should be reported by healthcare professionals and patients to Sanofi on 1800 818 806 or ae@sanofi.com. Alternatively, any suspected adverse events can be reported to the TGA at www.tga.gov.au/reportingproblems.

If you would like further information regarding BEYFORTUS nirsevimab 50 mg in 0.5 mL solution for injection pre-filled syringe please contact:

- For medical enquiries contact Sanofi Medical Information 1800 818 806
- For enquiries relating to supply contact Sanofi Customer Service 1800 829 468

Thank you for your understanding.
Regards,

Dr Iris Depaz
Head of Medical Sanofi Vaccines ANZ and Sanofi ANZ Medical Country Lead

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

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