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Vaxneuvance▼ (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)) suspension for injection in pre-filled syringe: Important information regarding the potential for breakage of Vaxneuvance pre-filled syringes.

Dear Healthcare Professional,

MSD in agreement with the European Medicines Agency and the MHRA would like to inform you of the following:

Summary

- **Breakage at the flange and/or hub of the syringe, resulting in lacerations or needle puncture wounds, have been reported for Vaxneuvance suspension for injection in pre-filled syringe.**

- **Further investigation has revealed that this is related to a component issue. While corrective and preventive actions have been implemented to address this defect, all Vaxneuvance syringes currently on the market have the potential for these defects.**

- **To reduce the potential risk of injury to the patient, caregiver and/or healthcare professional, it is recommended that the glass syringe be carefully inspected for breakage before use and the dose discarded if breakage is observed or suspected prior to use of Vaxneuvance.**

- **If no breakage is observed prior to use, during vaccine preparation and administration, healthcare professionals should avoid exerting excessive force on the syringe (including on the hub of the syringe) when removing the tip cap or attaching the needle to the syringe, or post-administration (e.g., when activating a needle safety mechanism), and during disposal.**

Background

Vaxneuvance is indicated for active immunisation for the prevention of invasive disease, pneumonia and otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents from 6 weeks to less than 18 years of age. It is also indicated for active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older.

Vaxneuvance is available as a suspension for injection in pre-filled syringe. MSD has received reports of breakage at the syringe flange and/or hub that were identified when the syringe was inspected before administration, while the healthcare professional was securing the needle to the syringe, during vaccine administration or post-administration (e.g., when activating a needle safety mechanism). The breakage resulted in a small number of injuries reported as non-serious, including laceration and needle puncture wounds.

Investigation conducted by MSD to date has determined the breakage to result from a step in the syringe manufacturing process that causes weakness in the glass and, when a subsequent force is applied, results in glass breakage. Actions have been implemented at the syringe manufacturer to improve processes and prevent these defects from recurring in future batches. However, all Vaxneuvance syringes currently in the marketplace have the potential for these defects to be present because the syringes were manufactured before corrective actions were implemented by the supplier.

The following recommendations are being proposed to help identify broken syringes before use and reduce the risk of injury. Please ensure that the staff in your institution involved in administering Vaxneuvance follow instructions available in the full product prescribing information and these additional instructions detailed

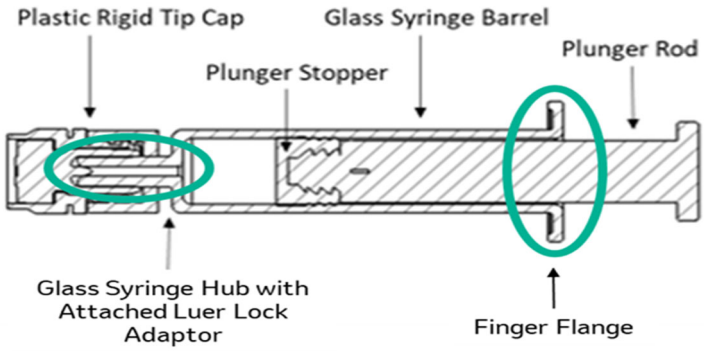
Prior to Use

- MSD recommends inspection of the syringe for breakage while in the package and after removal from the package.
- If breakage of the syringe is detected or suspected, please discard and do not attempt to administer the dose.

During Vaccine Preparation and Administration

- If no breakage is observed, proceed with administering the dose. Avoid exerting excessive force on the syringe, including on the hub of the syringe, when removing the tip cap, when securing the needle to the syringe, or post-administration (e.g., when activating a needle safety mechanism), and during disposal (Figure 1).

Figure 1.



Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Vaxneuvance▼ is subject to additional monitoring. This will allow quick identification of new safety information.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website: https://yellowcard.mhra.gov.uk
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number. Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Adverse reactions should also be reported to the company. Please report the product name and batch details.

Company contact points

For any questions or to report any product complaints or adverse events, please contact:

Great Britain:
Medical Information
Merck Sharp & Dohme (UK) Limited
Tel: +44 (0) 208 154 8000
e-mail:
medicalinformationuk@msd.com

United Kingdom (Northern Ireland):
Medical Information
Merck Sharp & Dohme Ireland
(Human Health) Limited
Tel: +353 (0)1 2998700
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Yours sincerely

Dr Dilruwan Herath
Executive Medical Director, UK & Ireland