



Our **commitment** is to **quality**

Ref: FSCA475/001

Date: 15<sup>th</sup> December 2022

**URGENT FIELD SAFETY NOTICE:**

**RISK of HARM from INGESTION of GEL SACHET**

|                          |   |
|--------------------------|---|
| <b>Device Name</b>       | VacSax Vommax Gel Emesis Bag pack of 50 |
| <b>Device Code (SKU)</b> | 9310-003                                |
| <b>UDI</b>               | 5055761601824                           |
| <b>LOT</b>               | ALL                                     |
| <b>ISSUE</b>             | IFU not being followed                  |

Dear Customer

Our records indicate that you have bought one or more VacSax Vommax Gel Emesis bag SKU# 9310-003

This letter is to inform you of corrective actions that will need to be performed to prevent issues that could lead to a hazardous situation if not supervised carefully.

**Description of the Issue:**

The VacSax Vommax Gel Emesis bag contains a sachet of absorbent polymer gel granules. On contact with liquid, the sachet granules absorb, expand and solidify the liquid. The gel granules are not toxic but if put in the mouth, they will expand in contact with saliva and therefore carry a risk of obstruction.

The VacSax Vommax Gel Emesis bag warnings include the following:

- **Do not leave unsupervised with patient.**
- **Do not eat. Seek immediate medical attention if swallowed.**

**Actions:**

1. Review this Field Safety Notice and attached Safety briefing and Awareness training record and ensure you are familiar with the content.
2. Customers should identify where the Vacsax Vommax Gel Emesis bag is in use with your organisation.



Our **commitment** is to **quality**

3. Bring this Field Safety Notice to the attention of anyone in your organisation with responsibilities for purchasing, policy, training and use relating to this product containing polymer gel granules.
4. Conduct a risk assessment on the areas or departments where the Vacsax Vommax Gel Emesis bags are being used, *taking into account the cognitive ability and age of patients* and determine whether the product is appropriate for use within the intended patient population and is used under the appropriate supervision.
5. Conduct awareness training with users of Vacsax Vommax Gel Emesis bags in areas where continued use is appropriate. ***Enclosed with this Field Safety Notice is a Safety briefing and Awareness training record.***

#### **Transmission of this Field Safety Notice:**

Please complete the Customer Response form and return as soon as possible by email to [glen.harper@vacsax.com](mailto:glen.harper@vacsax.com)

This Field Safety Notice needs to be distributed to those individuals who need to be aware within your organisation - or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting actions for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, VacSax cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

#### **Additional Comment**

If you have any further questions or require assistance completing the Customer Response Form at the end of this document, please contact me on [glen.harper@vacsax.com](mailto:glen.harper@vacsax.com). or [sales@vacsax.com](mailto:sales@vacsax.com)

Yours sincerely,

**Glen Harper**

**Quality Manager**

[glen.harper@vacsax.com](mailto:glen.harper@vacsax.com)



VacSax Limited  
 Western Wood Way  
 Langage Science Park  
 Plymouth PL7 5BG  
 United Kingdom

Telephone: +44 (0)1752 337000  
 Facsimile: +44 (0)1752 337600  
 Website: www.vacsax.com

Our **commitment** is to **quality**

**CUSTOMER RESPONSE FORM**

Reference: FSCA475/001

**Urgent Field Safety Notice  
 VacSax Vommax Gel Emesis bags SKU#9310-003**

Our records indicate that the VacSax Vommax Gel Emesis bag was delivered to your location. Please verify if you have any of the listed and complete the information below.

|                           |  |
|---------------------------|--|
| <b>Facility name</b>      |  |
| <b>Contact name/title</b> |  |
| <b>Full address</b>       |  |
| <b>Contact telephone</b>  |  |
| <b>E-mail address</b>     |  |

We have read the VacSax Vommax Gel Emesis bag, Field Safety Notice and we understand the communication and the required actions. If possible, please give estimated date of completion of corrective actions.

|                                  |  |
|----------------------------------|--|
| Form completed by:<br>PRINT NAME |  |
| Signature:                       |  |
| Position:                        |  |
| Date:                            |  |
| Proposed completion date:        |  |

Please send completed form to [glen.harper@vacsax.com](mailto:glen.harper@vacsax.com)

It is important that your organisation confirms that you have received this FSN and takes the actions detailed in the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.