BOTOX® Vial Sizes

- BOTOX® is available in three different vial sizes (50U, 100U and 200U)

50 Allergan Units

100 Allergan Units

200 Allergan Units

To prevent accidental overdose, care should be taken to use the correct amount of diluent (0.9% preservative-free saline) for the dosage chosen.

The amount of diluent varies between the different BOTOX® vial sizes.

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Potential Spread of Toxin

- Side effects related to spread of toxin distant from the site of administration have been reported, sometimes resulting in death.
  - Symptoms include exaggerated muscle weakness, dysphagia, dysphonia, dyspnoea & are consistent with the mechanism of action of botulinum toxin. These have been reported hours to weeks after injection.
  - Risk of symptoms is probably greatest in patients who have underlying conditions and comorbidities that would predispose them to these symptoms, including children and adults treated for spasticity, and who are treated with high doses
- Dysphagia ranges in severity from mild to severe, with potential for aspiration, which occasionally may require naso-gastric feeding

Please ensure continued monitoring for toxin spread reactions

For information on the full warnings and precautions, please refer to the Summary of Product Characteristics

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Physician Responsibilities

- Always refer to Summary of Product Characteristics (SmPC) when treating patients
- Ensure you have a benefit/risk discussion with the patient
- Discuss how to identify a reaction related to spread of toxin (e.g. difficulty with speech, swallowing or breathing) and the importance of contacting a doctor in this situation
- Please ensure the patient is given a copy of the Patient Information Leaflet (PIL)
- A leaflet is also available for patients
  - How to identify spread of toxin reactions and what the patient must do

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Reporting of suspected adverse reactions

- Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions by filling in a form online at:

  www.medicinesauthority.gov.mt/adrportal

  or at:

  203, Level 3,

  Rue D'Argens,

  Gzira GZR1368

  Alternatively, they may be reported to:

  Vivian Corporation Ltd

  29, Tower Street,

  Msida MSD1824

  Or by calling: +356 21344610