

SUPPLY OF DIPHTHERIA ANTITOXIN



DIPHTHERIA OUTBREAK WEBINAR

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GLOBAL SHORTAGE OF DIPHTHERIA ANTITOXIN



- Global supply of diphtheria antitoxin (DAT) is limited
- Increasing use of vaccine and declining incidence of the disease, caused the market for DAT to collapse, and with it the number of manufacturers.
- Only a few manufacturers have retained the procedures necessary to be able to provide the product
- The limited global supply may affect the availability of the required doses in a timely manner
- Current active suppliers*:

Instituto Butantan
(Brazil)

Premium Serums
(India)

ViNS Bioproducts
(India)

Biological E
(India)

Haffkine Bio-
Pharmaceutical
(India)

Scandinavian
Biopharma for HERA
(EU)

Bulbio
(Bulgaria)



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Information may have changed since last WHO reports

DIPHTHERIA ANTITOXIN TREATMENT



- DAT is an equine serum product that is the standard care for treatment of diphtheria cases
- DAT has significant impact on mortality and is more effective when administered earlier
- DAT should be administered **immediately** to probable cases with respiratory diphtheria (sore throat), low grade fever and adherent membrane (on tonsils, pharynx or nose). Do not wait for laboratory diagnosis
- Risk of complications and fatal outcome increases with delayed DAT administration
- Diphtheria antitoxin is not recommended in asymptomatic carriers or close contacts
- DAT is usually provided as lyophilized preparation containing 10 000 i.u. per vial.
- The treatment requires between 10 000 – 100 000 i.u. per patient, depending on severity or progression of the disease
- Due to risk of allergic reaction, ensure sufficient trained staff and equipment are available and the patient is cared for in an area where they can be monitored closely



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WHO Clinical management of diphtheria: guideline, 2 February 2024

NATIONAL SUPPLY PLAN



- No registered product in South Africa
- Requires Section 21 Authorisation
- Previously the Western Cape secured DAT supplies through a Section 21 process (Equity 21)
- WC also supplied their remaining DAT to Gauteng and Mpumalanga
- Mpumalanga in the process of securing own Section 21 authorisation
- There is a proposed plan for AMD to facilitate the procurement process at national level through either an RFQ or a Donation
- Provinces have been requested to quantify DAT needs for submission to AMD
- Procurement strategy will be discussed at the National Pharmaceutical Services Committee (NPSC) Meeting, 2-3 April 2025
- Once confirmed, supply plan to be shared with provinces



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Thank You



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