SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Tetanus Antitoxin B.P. – 1500 IU

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of ingredient	Quantity	Active/ Non-active	Reason for inclusion
Tetanus Antitoxin	1500 IU in 1 ml	Active	Active agent
Phenol	≤ 0.25%	Non-active	Preservative

3. PHARMACEUTICAL FORM – STRENGTH AND PACKING SIZE

Liquid for injection.1, 500 IU in 1.0 ml x 50 ml ampoule carton

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

Prophylactic use:

Tetanus antitoxin is to be given prophylactically to persons at risk with infected wounds, wounds contaminated with soil or mud, deep or punctured wounds and wounds with devitalising tissue damages. A dose of 1500 IU should be given subcutaneously or intramuscularly as early as possible after the wound is received. In severe wounds, the dose may be doubled or trebled and the antitoxin injected in two or three places around the wound. Prophylactic use is also to be recommended in case of surgical operations involving reopening of old scars, piles and fistuale and those in which- faecal contamination is likely.

Along with prophylactic passive immunization, it is advisable to initiate active immunization with adsorbed Tetanus toxoid.

Therapeutic use:

For therapy, large doses 100,000 - 200,000 IU of antitoxin should be given very slowly by intravenous route followed by smaller weekly doses intramuscularly as required. Some physicians prefer a smaller initial dose of 20,000 IU or so intramuscularly. Active immunization may be initiated when the patient is cured of the illness.

4.2 **Posology and Method of Administration:**

Prophylactic use:

Tetanus antitoxin is to be given prophylactically to persons at risk with infected wounds, wounds contaminated with soil or mud, deep or punctured wounds and wounds with devitalizing tissue damages. A dose of 1500 IU should be given subcutaneously or intramuscularly as early as possible after the wound is received. In severe wounds, the dose may be doubled or trebled and the antitoxin injected in two or three places around the wound. Prophylactic use is also to be recommended in case of surgical operations involving reopening of old scars, piles and fistuale and those in which- faecal contamination is likely.

Along with prophylactic passive immunization, it is advisable to initiate active immunization with adsorbed Tetanus toxoid.

Therapeutic use:

For therapy, large doses 100,000 - 200,000 IU of antitoxin should be given very slowly by intravenous route followed by smaller weekly doses intramuscularly as required. Some physicians prefer a smaller initial dose of 20,000 IU or so intramuscularly. Active immunization may be initiated when the patient is cured of the illness.

4.3 Contraindications:

4.4 Special Warnings and Special Precautions for Use:

4.5 Interactions with other Medicinal Products:

4.6 Pregnancy and Lactation:

4.7 Effects on the ability to drive and use machines:

4.8 Undesirable Effects:

In all cases, whether for prophylactic or therapeutic use, due precautions must be taken against possible allergic reactions as some individuals are likely to be sensitive to equine serum.

Although modern methods of refining the serum have reduced the incidence of allergic reactions a small percentage of persons who receive injections of foreign serum still develop such reactions. The reactions may develop within a few minutes of administration of serum or may take from a few hours to 10-12 days. The reaction is in most cases mild and evidenced by development of rashes like urticarial rash, itching, joint pains, slight oedema and varying degrees of local glandular swelling. The illness is seldom serious and rarely fatal.

In a very small minority of cases, however, a severe shock resembling an anaphylactic shock develops within a few minutes of administration of serum, and some of these cases, if not immediately and properly treated, may prove fatal. Amongst the immediate reactors there is often evidence of previous treatment with equine serum. Before giving the serum, therefore, it is always necessary to go into the previous history of the presence of allergic diseases like asthma, eczema, hay fever, etc., and also into the history of previous treatment with equine sera. Such patients should be treated with extreme care and caution.

In the case of all patients receiving Tetanus antitoxin serum, it is absolutely essential to test for hypersensitivity of the individual with a test dose.

The test dose should be administered with a small amount of the serum (0.2 ml of 1:10 dil.) either by subcutaneous or intra-cutaneous injection, If reaction develops within a few minutes indicating the existence of hypersensitivity, the serum should be given with great caution in small divided doses subcutaneously at regular intervals of half an hour. Intravenous administration of serum is not recommended in hypersensitive case.

In all cases receiving serum, the patient must be observed for an hour after the administration of serum, and Adrenaline injection (1: 1 000) must be kept ready at hand for immediate treatment of shock if it develops.

4.9 Overdose:

5.0 PHARMACEUTICAL PROPERTIES:

5.1 <u>Pharmacodynamic Properties</u>:

<u>Pharmacotherapeutic Group</u>: (ATC Code)

Immune sera

J06 A A02

Mechanism of Action:
Tetanus Antitoxin provides passive immunization against Tetanus infection.

Pharmacodynamic Effects:
Not applicable

Clinical Efficacy:
In the Clinical trial Tetanus Antitoxin is highly immunogenic and generally well Tolerated.

5.2 Pharmacokinetic Properties:
Not Applicable

5.3 Pre-clinical Safety Data:
No formal animal testing has been carried out for non-clinical assessment. However, as a part of the quality control every batch is tested in mice and guinea pigs for general safety.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:
Phenol

6.2 Incompatibilities:

6.3 Shelf Life:
24 months from the date of manufacture.

6.4 Special Precautions for Storage:
To be stored in the dark between 2-8°C. DO NOT FREEZE.

6.5 Nature and Contents of container:
1 ml white USP type I One Point Cut (OPC)
ampoule with liquid injection

6.6 Instructions for Use and Handling :

----

7. MARKETING AUTHORIZATION HOLDER

Serum Institute of India Private Limited

212/2, Hadapsar, Pune 411028
India
Telephone: ++ 91-20-6993900 / 04
Fax: ++ 91-20-6993924 / 6993921

8. MARKETING AUTHORIZATION NUMBER (S)

SI/IND/001

9. DATE OF FIRST AUTHORIZATION / RENEWAL

Date of first Authorization: 30th June 1988

Date of latest renewal: 24th July 2021

10. DATE OF REVISION OF TEXT

July 2023