Mixed Gas-gangrene Antitoxin B.P.

GANGREVIN

10mL

Enzyme refined, equine derived mixed gas gangrene antitoxic immunoglobulin fragments

Composition:

Enzyme refined, equine derived mixed gas gangrene antitoxic immunoglobulin fragments, Each mL contains:
Gas-gangrene Antitoxin *(Clostridium oedematiens)* not less than 1,000 I.U.
Gas-gangrene Antitoxin *(perfringens)* not less than 1,000 I.U.
Gas-gangrene Antitoxin *(septicum)* not less than 500 I.U.
Cresol B.P. < 0.25% v/v as preservative
Excipients : Sodium Chloride B.P.
Stabilizer : Glycine B.P.

Description

Mixed Gas-gangrene Antitoxin is composed of purified polyvalent protein fractions derived from the equine plasma containing specific immunoglobulins. The Antitoxin contains purified Immunoglobulin Fragments (F(ab)2) with Cresol < 0.25% v/v as a preservative. The Antitoxin is supplied as a liquid polyvalent formulation. One vial in the pack contains mixture of anti-toxins against 3 causative agents, which are common for clinical cases of gas gangrene.

Pharmacodynamic/Pharmacokinetics

Not applicable.

Indications

For prophylaxis (Sepsis, Oedema, Necrosis caused due to Clostridium perfringens, Clostridium oedematiens, Clostridium septicum) and Treatment of Gas-gangrene.

The preparation is used for prevention and treatment of gas gangrene. As a preventive measure the antitoxin is administered intramuscularly, whereas therapeutic administration is performed by means of intravenous infusion.

Biological and immunobiological properties

Therapeutical effect of Poly Valent Mixed Gas-gangrene Antitoxin is provided by the specific antibodies contained in the preparation. The antibodies selectively neutralize the toxins derived by anaerobic microbes (A-type Clostridium perfringens, Clostridium oedematiens and Clostridium septicum).

Directions

Mixed Gas-gangrene Antitoxin may be used both to treat or prevent development of the "gas gangrene" resulted from septic infections such as anaerobic sepsis. Prior to administration, the individual sensitivity must be taken with intracutaneous injection of (0.1 ml), administered to the inner elbow area. The reaction is recognized as negative, if in 30 min the area of injection spot appears reddish having less than 1 cm in diameter. Antitoxin has to be administered to the patient in the possibly shortest time after getting injuries. Prophylactic dose may be administered with intramuscular injection. If the reaction of individual sensitivity shown as positive (> 1 cm in diameter) then the product must be administered gradually with several dilutions of 0.1 ml of Antitoxin in 9.9 ml of Physiological saline solution. The doses to test allergic response are 0.5 ml, 2 ml and 5ml. If these doses are well tolerated then the final test is performed with intramuscular injection of 0.1 ml of Gas-gangrene Antitoxin followed by complete therapeutic dose.
Clinical treatment of gangrene with the Antitoxin is featured as a slow intravenous infusion of the Antitoxin (25000 I.U.

Contraindications

There are no known contraindications to use the preparation of Mixed Gas-gangrene Antitoxin.

Side effects and Reactions to the Antitoxin

In some cases, the administering of the Antitoxin might be associated with side effects, which can be divided into the three classes: short term reaction may develop right after the Antitoxin injection; mid-term reaction may develop in 4 to 5 days after the treatment and time-delayed reaction (becomes detectable in 2 or more weeks after injecting the Antitoxin). Those reactions may correspond with symptoms of fever, chills, light convulsions, skin rash and minor impairments of cardiac-vascular activity. Such an effects may last from several hours to several weeks (very rare the person's collapse might be observed). If the Mixed Gas-gangrene Antitoxin injection is followed by development of anaphylactic reaction or the other shock symptoms, the patient should immediately be administered with subcutaneous injection of adrenaline (1:1000; 0.3-1 ml) or ephedrine (5%; 0.1-1 ml), depending on the person's age. In the severe cases the intravenous administrating of these drugs might be recommended. Further guidelines and recommendations include intravenous administrating of Novocain (0.5% solution; 1-8 ml), calcium chloride (10% solution; 3-10 ml) and glucose solution (20-40%; 20-50 ml). Hormone drugs like prednisolone, prednisone, hydrocortisone and the others like cordiamine, caffeine, camphora might be recommended too. Upon the severity of the patient's shock condition could be considered the treatment with slow intravenous infusion of 0.9% w/v NaCl (300-500 ml) supplied with 0.3-0.5 ml of adrenaline (1:1000).

Packing and Presentation

Mixed Gas-gangrene Antitoxin 10mL is a liquid preparation that is supplied in a vial. Each package contains the vial along with the package insert.

Storage: Store at a temperature between 2°C to 8°C in a refrigerator. Do not freeze.

Disposal: Left over contents and used empty vials should be discarded as biomedical waste.

Manufactured by:
ViNS BIOPRODUCTS LIMITED
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Telangana, India.

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