Abbreviated Prescribing Information – Inoscorpi ™ MENA - For full prescribing information see the approved Summary of Product Characteristics (SPC)

Product name: Inoscorpi™ MENA. Polyvalent F(ab')$_2$ Immunoglobulin Fragments (Equine), Scorpion Antivenom. **Composition:** less than 100 mg of total proteins (< 10%) composed of equine F(ab')$_2$ immunoglobulin fragments neutralizing with high specificity the venoms of Norh-Africa and Middle-East species (list of species detailed hereafter). Excipients: sodium chloride, glycine, sucrose. **Pharmaceutical form:** lyophilized powder for injectable solution. **Indications:** Inoscorpi ™ MENA is indicated for the treatment of envenoming caused by the stings of the following species: *Androctonus australis, Androctonus mauritanicus, Androctonus crassicauda, Androctonus amourexi, Androctonus bicolor. Buthus occitanus, Buthus mardochei, Buthus tunetanus, Leiurus quinquestriatus quinquestriatus, Leiurus quinquestriatus hebraeus.*

Dosage and administration: Inoscorpi™ MENA should be administered as soon as the first signs of envenoming appear, which may include local pain, fever, digestive disorders (nausea, vomiting, abdominal bloating, diarrhea), neurological disorders (somnolence, agitation, fasciculation of the stung limb, hypersalivation, convulsion, coma), cholinergic syndrome (vomiting, salivation, heavy sweating, tearing, miosis, priapism, bronchial disease, bradycardia), adrenergic storm (tachycardia, peripheral vasoconstriction, arterial hypertension, mydriasis), cardiac disorders and respiratory disorders. **Initial dose should be 1 vial**. Following the administration of the initial dose, it is recommended to evaluate the patient **every 2 to 4 hours**. If major envenoming symptoms persist, get worse or start to appear, **treatment (1 vial) should be repeated**. Regular follow-up evaluations should be performed to determine the need for repeating treatment until the critical clinical symptoms of envenoming have resolved. Larger quantities of antivenom may be required depending on the amount of inoculated venom, the severity of envenoming, the general condition of the patient, the patient's clinical evolution and the scorpion species involved. In contrast, the age, sex or weight of the patient should not be considered in assessing the quantity of antivenom to deliver. **Reconstitution** of the product should be performed immediately prior to administration. Do not store any reconstituted product. The lyophilized powder should be diluted with 10 ml of Sterile Water for Injection (ampoule provided in the pack). The water should be introduced in the vial containing the powder using proper sterile techniques. The dissolution of the product is obtained in no more than 60 sec after a gentle shaking. The appearance of the solution should be clear to light yellow in color and slightly opalescent with no foreign particles in suspension. If the product is not fully dissolved and contains remaining foreign particles, it should be discarded and another vial should be used instead. **Administration** of Inoscorpi ™ MENA is performed through **intravenous injection.** The preferred route of administration is **direct intravenous injection** of of each 10 ml solution **slowly over a minimum of 3 minutes per vial**. The product can also be administered through **a drip** (1 vial of 10 ml reconstituted solution diluted with 50 ml of sterile isotonic saline solution) **over 30** minutes. **Contraindications:** known history of allergy to equine proteins or excipients. Considering the fatal risk linked to envenoming, allergy to equine proteins is not a contraindication to the use of antivenom, provided that treatment for anaphylactic shock can be implemented immediately, if necessary. **Special warnings and precautions for use:** patients with known allergies to equine origin proteins have a higher risk of experiencing hypersensitivity reactions, as well as the patients who have received prior treatment with Inoscorpi™ MENA or other equine origin antivenoms that might have caused hypersensitivity to equine origin proteins. Envenoming in children generally leads to more severe symptoms and a higher rate of lethality and sequelae. This is due to children's smaller body weight and volume that lead to a lower dilution of venom. Dosage should be the same for adults and children, irrespective of patient weight. **Pregnancy and breastfeeding:** Considering the fatal risk linked to envenoming, pregnancy and breastfeeding are not contraindications to the use of antivenom. **Fertility:** there is no evidence and there are no reports or fertility problems

with the use of Inoscorpi™ MENA. **Effects on ability to drive and use machines:** not relevant. **Undesirable effects:** As any medication, Inoscorpi™ MENA may be associated with side effects during its administration. As with other pharmaceutical preparation of equine origin $F(ab')_2$ fragments, it is possible to experience immediate or delayed allergic reactions.
Acute reactions: The administration of equine origin $F(ab')_2$ fragments may be associated with allergic reactions including sweating, nausea, rashes, modest fall in blood pressure; these reactions are generally of mild intensity. Anaphylactoid reactions with hypertension, dyspnea, urticaria, Quincke's edema or severe allergic shock may also occur. However, the actual generalized allergic shock only appears in an exceptional manner. In this case it is recommended to immediately suspend the infusion and to administer corticosteroids, diphenhydramine hydrochloride, as well as any therapy that the healthcare provider deems appropriate. Serum sickness: Similar reactions to serum sickness have been described after the administration of animal origin proteins that may appear roughly 6 days after treatment onset. The clinical signs are fever, pruritus, erythema or urticaria, adenopathy and arthralgias. However, these types of reactions are observed in less than 1% of the patients who are given equine origin $F(ab')_2$ fragments. **Adverse events** should be reported at: pharmacovigilance@inosanbiopharma.com. **Overdose:** due to the nature of Inoscorpi™ MENA, no overdose effects are expected. **Shelf life:** 36 months. **Special precautions for storage:** the product should be stored at room temperature (between 8°C and 30°C). Temperature excursions exceeding 30°C are permitted up to 40°C for a maxim period of 6 months. Do not freeze. **Marketing Authorisation Holder:** INOSAN BIOPHARMA, S.A. Arbea Campus Empresarial, Edificio 2. Planta 2, Carretera Fuencarral a Alcobendas, Km.3.8-28108, Alcobendas, Madrid – SPAIN. **Legal category:** POM. **Date of revision of the text:** 15/04/2020