Summary of Product Characteristics

1. Name of the medicinal product

Rabix-IG

Rabies Immunoglobulin USP

Available in1000 IU/5 ml strength.

2. Qualitative and quantitative composition

Each vial contains Rabies immunoglobulin USP (as Equine anti rabies immunoglobulin fragments) ≥1000 IU/ 5 ml.

3. Pharmaceutical form

Rabix-IG is a sterile, non-pyrogenic solution for intra-muscular administration, containing antiviral substances obtained from the blood serum of healthy equines that have been immunized against rabies by vaccination. In addition, it also contains the anti-microbial agent cresol. Clear , colourless or pale yellow liquid and free from any visible particle.

4. Clinical particulars

4.1 Therapeutic indications

For the seroprophylaxis (prevention by injecting antibodies) of rabies in subjects suspected to have been exposed to the rabies virus, particularly in the event of severe exposure e.g.:

- Multiple transdermal bites or scratches
- Contamination of mucous membrane with saliva
- Severe bites located on the face, head, neck and hands
- When the domestic or wild animal responsible cannot be examined or is infected or suspected to be infected by the rabies virus
- Bites to young children

Rabix-IG provides passive immunization against rabies for prevention of rabies in patients after contact with a rabid animal or an animal presumed to be rabid. Anti rabies serum itself does not constitute an anti rabies treatment and should always be used in conjunction with rabies vaccine.

4.2 Posology and method of administration

First-aid treatment: Prompt local treatment of bite wounds and scratches that may be contaminated with rabies virus is important, whatever the time elapsed since the contact. The recommended first-aid

measures consist of immediate flushing and washing of the wound with soap and water, detergent or other substance of proven lethal effect on rabies virus. The rabies immune globulin should be injected as soon as possible after exposure.

The recommended dose for both adults and children is 40 IU/kg of body weight. If anatomically feasible, as much as possible of the dose should be infiltrated around and into the wound(s).

The remainder should be administered intramuscularly (into the gluteal region) in a single injection.

However, for children, particularly in the case of multiple wounds, it has been proposed to dilute the dose 2-3 times in a 0.9% sodium chloride solution to obtain a sufficient quantity of equine rabies immunoglobulin to infiltrate the wound(s) correctly. Wounds in certain anatomical sites (fingertips) should be infiltrated with care so as to prevent a local increase in pressure in the tissue.

For prevention of rabies, combined immunoglobulin-vaccine treatment is recommended. The 1st dose of the rabies vaccine should be given at the same time as the Rabix-IG, but in different parts of the body. If Rabix-IG is not available when the rabies vaccine is administered, it can be administered up to the 7th or 8th day after the first dose of rabies vaccine. When indicated, begin anti-tetanus treatment and administer anti-microbial drugs to control infections other than rabies.

The WHO expert committee on rabies has issued the following therapeutic recommendations:

Category	**Type of contact with a suspect or confirmed rabid domestic or wild animal or animal not available for observation**	**Recommended Treatment**
1.	Touching or feeding of animal, licks on intact skin	None, if reliable case history is available
2.	Nibbling of uncovered skin, minor scratches superficial bites (except on head, neck, shoulder girdle,arms or hands) or abrasions without bleeding, licks on broken skin.	Administer vaccine immediately on Day 0, D3, D7, D14 and D28.Stop treatment if animal remains healthy throughout the observation period of 10 days or if animal is killed humanely and found to be negative by appropriate laboratory techniques.
3.	Single or multiple transdermal bites or scratches specially on head, neck, shoulder girdle, arms or hands.	**Administer rabies vaccine immediately on Day 0, D3, D7, D14 and D28 or D90 (optional) and rabies immunoglobulin on D0 immediately**. Stop treatment if animal remains healthy throughout

	Contamination of mucus membrane with saliva (i.e. licks on broken skin).	the observation period of 10 days or if animal is killed humanely and found to be negative by appropriate laboratory techniques.

4.3 Contraindication

Known history of allergic symptoms to horse proteins. Nevertheless, the lethal risk associated with rabies overcomes any potential contraindication.

4.4 Special warnings and precautions for use

Do not administer rabies immunoglobulin intravenously (due to the risk of shock i.e., sudden collapse with drop in blood pressure). Consequently, make sure that the needle has not penetrated a blood vessel.

Rabies immune globulin should not be administered in repeated doses. Once the vaccine treatment has been started, repeating injections of rabies immunoglobulin may reduce the protective efficacy that must be guaranteed by the vaccine.

Shake well before use. Do not shake vigorously.

4.5 Interaction with other medical products and forms of interaction

For treatment associating rabies immunoglobulin and rabies vaccine, the rabies vaccine should be injected in a contralateral anatomic site (i.e., on opposite side) using a different syringe. As a general rule, corticosteroids, liable to attenuate the immune response, should be avoided.

4.6 Fertility,Pregnancy and lactation

Pregnancy

The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.

Breast-feeding

Immunoglobulins are excreted in human milk and may contribute to protecting the neonate from pathogens which have a mucosal port of entry.

Fertility

No animal fertility studies have been conducted with human rabies immunoglobulin. Clinical experience with immunoglobulin suggests that no harmful effects on fertility are to be expected

4.7 Effects on ability to drive and use

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

Immediate or delayed hypersensitive type reactions may be developed on administration of rabies immunoglobulin. The observed immediate reactions are hypotension, dyspnoea, and urticaria. Delayed reactions consist of inflammatory reaction, fever, pruritis, rash or urticaria, adenopathy and arthralgia.

4.9 Overdose

If the recommended dosage is not strictly observed, there is a risk of immunosuppressive interference (suppression of immune defenses) with rabies vaccine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.1.1 Pharmacotherapeutic group:

Immunoglobulin

5.2 Pharmacokinetic properties

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

Cresol

Water for Injection

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years from the date of manufacturer when stored at 2 – 8 °C

6.4 Special precautions for storage

- Keep out of the reach and sight of children
- Store at + 2°C and + 8°C. Transportation should also be at 2°C and + 8°C
- Protect from light
- Do not freeze

6.5 Nature and contents of container

Each box contains 1 vial of rabies immunoglobulin and a sterile disposable syringe.

6.6 Special precautions for disposal and other handling

The medicinal product should be brought to room or body temperature before use.

Do not use solutions that are cloudy or have deposits.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder

Incepta Vaccine Ltd. Dhaka, Bangladesh

8. Market authorization number(s)

MA363-0014-069

9. Date of first authorization/Renewal of the authorization

30 November, 2017

10. Date of revision of the text

May, 2021