PRODUCT INFORMATION

IMOGAM RABIES PASTEURIZED - HUMAN RABIES IMMUNOGLOBULIN

COMPOSITION

1 ml of human rabies immunoglobulin contains:

Active ingredient:

- Human proteins 100 –180 mg

  containing (IgG class) human rabies immunoglobulins with a minimum titre of 150 I.U.

Other ingredients:

- Glycine 22.5 mg
- Sodium chloride 1 mg
- Water for injections up to 1 mL

PHARMACEUTICAL DOSAGE FORM

Injectable solution.

- Vial of 2 ml containing at least 300 I.U. human rabies immunoglobulins.
- Vial of 10 ml containing at least 1500 I.U. human rabies immunoglobulins.

INDICATIONS

IMOGAM RABIES PASTEURIZED is indicated in subjects who are thought to have been exposed to rabies virus, especially cases of major exposure, in accordance with W.H.O. recommendations.

Category	Type of contact with a suspect or confirmed rabid domestic or wild animal, or animal unavailable for observation	Recommended treatment
I	Touching or feeding of animals. Licks on intact skin.	None if reliable case history is available.
II	Nibbling of uncovered skin. Minor scratches or abrasions without bleeding. Licks on broken skin.	Administer vaccine immediately. Stop treatment if animal remains healthy throughout an observation period of 10 days or if animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques.
III	Single or multiple transdermal bites or scratches. Contamination of mucous membrane with saliva (i.e. licks).	Administer rabies immunoglobulin and vaccine immediately. Stop treatment if animal remains healthy throughout an observation period of 10 days or if animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques.

W.H.O. Expert Committee on rabies, 1992; 824: 55

For rabies prevention in category III situations, combined treatment with immunoglobulin and vaccine is absolutely essential.

Sole exception: subjects who have been immunized beforehand with rabies vaccine and who present confirmed titres of antirabies antibody should receive the vaccine only.

IMOGAM RABIES PASTEURIZED should be administered exclusively in combination with rabies vaccination.

It is imperative that administration should take place under medical supervision in accordance with currently applicable national legislation.

CONTRAINDICATIONS

The mortal risk associated with rabies outweighs any possible contraindication (cf warnings).

If you are unsure, it is essential to seek the advice of your doctor or pharmacist

SPECIAL WARNINGS

This medication is a blood derivative

Do not administer this product intravenously (risk of shock): ensure that the needle has not penetrated a blood vessel.

Allergic reactions to human rabies immunoglobulins administered intramuscularly are rare. In the event of shock follow the standard guidelines for the treatment of shock. The patient must be kept under supervision for at least 20 minutes after administration.

PRECAUTIONS FOR USE

Do not administer this product intravenously (risk of shock).

Use this medication WITH CARE in patients who are known to be allergic to one of the constituents of this product.

If you are unsure, do not hesitate to seek the advice of your doctor or pharmacist.

DRUG INTERACTIONS AND OTHER INTERACTIONS

Rabies vaccine:

Repeated doses of IMOGAM RABIES PASTEURIZED should not be administered once the vaccination program has been started. Repeated doses of human rabies immunoglobulin may in fact reduce the peak active immunity normally conferred by the vaccine.

Attenuated live viral vaccines:

Administration of immunoglobulins may interfere with the efficacy of vaccines containing attenuated live viruses such as measles, rubella, mumps and chickenpox vaccines. After injection of IMOGAM RABIES PASTEURIZED wait at least 6 weeks (preferably 3 months) before administering other attenuated live vaccines.

If the patient has received attenuated live viral vaccines in the previous two weeks (measles, rubella, mumps, chickenpox), determination of the post vaccination protective antibody level (3 months after receiving IMOGAM RABIES PASTEURIZED) may be useful before deciding on the need for an additional dose.

Interference with serological tests:

After an injection of immunoglobulins, a temporary rise in various antibodies passively transferred to the patient may give rise to false positive results in serological blood tests.

In order to avoid the possibility of interaction between several medications, you should systematically inform your doctor or pharmacist of any other treatment you are currently taking.

PREGNANCY - BREAST FEEDING

The safety of this medication during pregnancy has not been established by controlled clinical trials.

Immunoglobulins are excreted in maternal milk and may help to transfer protective antibodies to the infant.

DRIVERS AND MACHINE USERS

There is no evidence that IMOGAM RABIES PASTEURIZED hampers the ability to drive or use machines.

DOSAGE AND MODE AND ROUTE OF ADMINISTRATION

IMOGAM RABIES PASTEURIZED should be administered exclusively in combination with rabies vaccination but different sites and from different needles (for the first dose of vaccine).

It is imperative that administration should take place under medical supervision in accordance with currently applicable national legislation.

Dosage:

The recommended dose of IMOGAM RABIES PASTEURIZED is a single intramuscular administration of 20 I.U./kg body weight at the same time as administration of the first dose of vaccine (see mode and route of administration). This dose must not be exceeded under any circumstances since immunoglobulin can partially suppress active antibody production.

If initiation of treatment is delayed for any reason, IMOGAM RABIES PASTEURIZED should still be given regardless of the interval between exposure and treatment up to the eighth day after the first dose of vaccine.

The dose of 20 I.U./kg body weight is the same for children and adults. In children, especially following multiple wounds, the dose of IMOGAM RABIES PASTEURIZED may be diluted 2- to 3-fold in a solution of 0.9 % sodium chloride in order to provide the full amount of human rabies immunoglobulin required for good infiltration sites at risk of rabies.

Mode and route of administration:

Treatment of the wound is very important and must be performed as soon as feasible after the bite and irrespective of the amount of time lapsed since contact. The wound should be cleansed with copious amounts of water, soap and detergent, and then disinfected with quaternary ammonium compounds.

In addition to local treatment, tetanus prophylaxis and measures to prevent bacterial infection, it is necessary to immediately immunize with the rabies vaccine at another body site (preferably the deltoid area).

If administration is anatomically feasible, the largest possible proportion of the dose should be administered by infiltrating around the wound(s). The remainder should be administered intramuscularly (into the buttocks) a single dose.

IMOGAM RABIES PASTEURIZED should not be administered using the same syringe or at the same anatomical as rabies vaccine.

How often and when to administer:

If initiation of treatment is delayed for any reason, IMOGAM RABIES PASTEURIZED should still be given regard of the interval between exposure and treatment up to the eighth day after the first dose of vaccine.

How long to administer:

Only a single intramuscular administration of IMOGAM RABIES PASTEURIZED should be given. Repeated doses of IMOGAM RABIES PASTEURIZED should not be given once the vaccination program has been started. Repeated dose of human rabies immunoglobulin may in fact reduce the peak active immunity normally conferred by vaccine.

WHAT TO DO IN OVERDOSE

There is no recorded case of overdose with IMOGAM RABIES PASTEURIZED. This dose should not be exceeded under any circumstances since immunoglobulin may partially suppress the active production of antibody.

WHAT TO DO IF ONE OR SEVERAL DOSES HAS BEEN OMITTED

If initiation of treatment is delayed for any reason, IMOGAM RABIES PASTEURIZED should still be given regardless of the interval between exposure and treatment up to the eighth day after the first dose of vaccine.

SIDE EFFECTS

Pain and discomfort have been observed at the injection site; these local reactions may be minimized by administration of smaller volumes at more closely approximated sites.

Infiltration of wounds in some anatomical sites (finger tips) must be carried out with care in order to avoid any increase pressure in the tissue compartment (compartment syndrome). Fever, skin reactions or chills may sometimes appear with human rabies immunoglobulins. Rare cases of nausea vomiting, hypotension, tachycardia and allergic-type reactions have been reported. In very rare cases, reactions as severe as anaphylactic shock have been observed. In such an event, a suitable symptomatic treatment should initiated.

The risk of transmitting infectious agents cannot be definitively excluded when medications prepared from human blood or plasma are administered. This risk also applies to as yet unknown pathogens.

This risk is however limited by:

- strict control procedures when selecting donated blood by means of a medical questionnaire of donors and screening tests on each unit donated, in particular for the following viruses. HIV_1, HIV_2, HCV, HBV;
- the extraction/purification process which includes viral elimination (precipitation in alcohol) and inactivation (pasteurization for 10 hours at 60°C) stages, the effectiveness of which has been validated using virus models for the above-listed viruses based on parvovirus B19 and human herpes viruses.

Inform your doctor or pharmacist of any unusual or troublesome effect which is not mentioned in this package insert

STORAGE

Do not exceed the expiry date displayed on the external packaging.

SPECIAL PRECAUTIONS FOR STORAGE

Keep at a temperature of between + 2°C and + 8°C (in the refrigerator) and protected from light. Do not freeze.

The product must be used immediately after opening.

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POISON SCHEDULE
S4 – Prescription Only Medicine

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01 February 2000

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