1. WHAT HUMAN RABIES IMMUNOGLOBULIN IS AND WHAT IT IS USED FOR

This product is a solution containing a large quantity of rabies antibodies. It is prepared from blood plasma from screened donors and virally-inactivated during manufacture. It is used to protect you against rabies and is given with first dose of rabies vaccine, or not more than 7 days later. Your doctor will explain further why this medicine has been given to you.

This product is usually given to you if:
- you have been bitten, scratched or received any other injury from a suspected rabid animal or you may have swallowed or breathed in tissue such as saliva from a suspected rabid animal.

Human Rabies Immunoglobulin is given by injection around the wound and into the muscle at the side of the thigh (intramuscular). Your doctor or nurse will give you the injection.

2. BEFORE YOU ARE GIVEN HUMAN RABIES IMMUNOGLOBULIN

Special care must be taken with Human Rabies Immunoglobulin if you:
- develop an allergic reaction (see Section 4 'Possible Side Effects' for a list of these). If you suffer from any of these, or just feel unwell, tell your doctor.
- suffer from a blood disorder. Inform your doctor before this medicine is injected. Your doctor or nurse may inject this product just under the skin under these circumstances.
- have had any vaccinations recently or know you are about to have any vaccinations. Tell your doctor if this is the case.
- have had this product recently as it may give misleading results if you have a blood test. Inform your doctor if this is the case.
- have already had this product recently. Tell your doctor as the previous injection may interfere with rabies vaccine.

Taking other medicines
Please tell your doctor if you are taking, or have recently taken, any other medicines, including those obtained without a prescription. This solution for injection must not be mixed with other medicinal products for injection. Your doctor will advise you about any vaccinations you may need in addition to giving you this product.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant, think you may be pregnant or are breastfeeding before this medicine is injected.

Driving and using machines
There are no known effects of this product on your ability to drive or operate machinery.

3. HOW YOU ARE GIVEN HUMAN RABIES IMMUNOGLOBULIN

This product must be injected by a doctor or nurse. Human Rabies Immunoglobulin must not be injected into a vein. It is for injecting around the bite wound and the rest of the dose into the side of the thigh.

Doses
20 IU/kg body weight at the same time as the first dose of rabies vaccine or not more than 7 days later. Your doctor will advise you on the dose for you.
4. POSSIBLE SIDE EFFECTS

As with all medicines, Human Rabies Immunoglobulin may cause side effects, although not everybody gets them. Allergic reactions can occur, which may include tightening in the throat or chest, tongue swelling, swelling beneath the skin particularly around the lips and eyes, hives (urticaria), wheezing or flushing. These can progress to shock. There may be some short term discomfort at the site of injection. Very rarely a hardened area may develop where the injection was given.

The following have been reported after injection:

- chest pain, shortness of breath, shaking, dizziness, swelling of the face, coating of the tongue, mouth ulcers, joint pains.

If you get any of these or continuous pain, itching, rash or any other reaction or just feel unwell, you must tell your doctor.

Please note

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include:

- careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded,
- the testing of each donation and pools of plasma for signs of virus/infections, – the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded.

This also applies to any unknown or emerging viruses or other types of infections. The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the nonenveloped hepatitis A and parvovirus B19 viruses. Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product, are protective.

5. HOW TO STORE HUMAN RABIES IMMUNOGLOBULIN

- Keep out of the reach and sight of children.
- You should store the medicine in its carton to protect it from light, in the refrigerator (2-8°C). Do not freeze. Short periods (up to one week) of storage at room temperature (25°C), in the dark, will not damage the product.
- Do not use the medicine after the expiry date which is printed as “EXP” on the containers (the expiry date refers to the last day of the month stated).
- Do not use the medicine if it is cloudy or any small bits can be seen in it.

Disposal

After injection of the correct dose, dispose of any solution that remains, along with used syringes, needles and containers. Your doctor will do this.

Medicines should not be disposed of via wastewater or household waste.

6. FURTHER INFORMATION

What Human Rabies Immunoglobulin contains

The active substance is immunoglobulin containing a specifically high concentration of antibodies (not less than 150 IU/mL) to the rabies virus.

The other ingredients are: glycine, sodium chloride, sodium acetate and a small quantity of sodium hydroxide.

What Human Rabies Immunoglobulin looks like and the contents of the pack

Human Rabies Immunoglobulin is a clear to slightly cloudy, colourless to pale yellow sterile solution, available as single dose vials containing 500 IU in glass vials. These vials are closed with a synthetic rubber stopper, held on by an aluminium ring and flip off cover.

Marketing Authorisation Holder and manufacturer

Bio Products Laboratory Limited, Dagger Lane, Elstree, Hertfordshire, WD6 3XH, United Kingdom.

Marketing Authorisation Number PL 08801/0014

For further information or if you have any questions about the use of this product, please contact BPL via the Marketing Department at the address above or through info@bpl.co.uk.

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