Please read all of this leaflet carefully before using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor. Is this leaflet hard to see or read? Phone 020 8258 2200.

In this leaflet:
1. What Human Varicella-Zoster Immunoglobulin is and what it is used for
2. Before you use Human Varicella-Zoster Immunoglobulin
3. How to use Human Varicella-Zoster Immunoglobulin
4. Possible side effects
5. How to store Human Varicella-Zoster Immunoglobulin
6. Further information

1. WHAT HUMAN VARICELLA-ZOSTER IMMUNOGLOBULIN IS AND WHAT IT IS USED FOR

Varicella-zoster is a virus which causes chicken pox (varicella) and shingles. This product is a solution containing a large quantity of varicella-zoster immunoglobulin (antibodies) which the body produces to provide protection against infection with this virus. It is prepared from blood plasma from screened donors.

Human Varicella-Zoster Immunoglobulin is given by injection into a muscle (intramuscular) such as the buttock or thigh. It is used to protect against infection by the varicella-zoster virus (VZV). Your doctor will explain further why this medicine has been given to you.

This product is usually given to:

- newborn babies whose mothers develop chickenpox (varicella) within 7 days before and 7 days after baby’s birth
- It is also given to the following individuals who have come into contact with a person who has chickenpox or shingles:
- pregnant women with no antibodies to VZV especially up to about 30 weeks of pregnancy
- newborn babies whose mother has never had chickenpox (varicella) and/or is not immune
- premature infants less than 28 weeks of gestation or newborns with low birth weight
- adults and children who have never had chickenpox (varicella) and/or are not immune, and whose immune response is reduced by certain medicines such as steroids, anti-cancer drugs or by certain treatments such as radiotherapy or recent stem cell transplantation
- adults and children who have a reduced immune system which makes them more likely to have infections such as chicken pox or shingles unless they are receiving other types of regular immunoglobulin treatment.

2. BEFORE YOU ARE GIVEN HUMAN VARICELLA-ZOSTER IMMUNOGLOBULIN

You must not be given this medicine if you are:

- allergic to human immunoglobulins
- allergic to any of the ingredients in this product (see Section 6, ‘Further Information’ for a list of these).

Special care must be taken with Human Varicella-Zoster Immunoglobulin if you:

- develop an allergic reaction (see Section ‘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 you 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. Tell your doctor if this is the case.

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 breast-feeding 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 TO USE HUMAN VARICELLA-ZOSTER IMMUNOGLOBULIN**

This product must always be Injected by a doctor or nurse. Human Varicella-Zoster Immunoglobulin must never be injected into a vein and must be injected slowly into a large muscle such as the buttock or thigh. Human Varicella-Zoster Immunoglobulin may be injected just under the skin, your doctor will advise on this or may use an alternative intravenous product.

**Doses**

At least 15 µg body weight should be given as soon as possible, ideally within 3 days but certainly within 10 days of a contact with a person who has chickenpox or shingles.

As a guide, alternative dose levels for treatment are as follows:

- 0 - 5 years: 250 mg (1 vial)
- 6 - 10 years: 500 mg (2 vials)
- 11 - 14 years: 750 mg (3 vials)
- 15 years and older: 1,000 mg (4 vials)

If a second contact with a person who has chickenpox or shingles occurs three weeks or more after the first dose, a second dose must be given.

**4. POSSIBLE SIDE EFFECTS**

As with all medicines, Human Varicella-Zoster Immunoglobulin may cause side effects, although not everybody gets them. There may be some short term swelling, warmth, pain, redness, wound itching or rash at the injection site. A hardened area may develop where the injection was given.

The following may also occur after injection:

- allergic reactions, which may be serious with difficulty in breathing or dizziness
- lightheaded, fainting or feeling faint
- rapid heartbeat
- headache
- chills, fever
- itching, redness of the skin

If you get any of these or notice any side-effects not listed in this leaflet, 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, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include 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.

Immunoglobulins have not been associated with hepatitis A or parvovirus B19. 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.

It is strongly recommended that every time you receive a dose of Human Varicella-Zoster Immunoglobulin the name and batch number of the product are recorded in order to maintain a record of the batches used.

**Please remember**

Since chicken pox in pregnancy, in newborn babies or in patients whose immune system is not working fully can have serious effects on health, the expected benefits of your medicine will usually be greater than the risks of suffering any harmful side effects.

5. **HOW TO STORE HUMAN VARICELLA-ZOSTER 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, your doctor or nurse will dispose of any solution that remains, along with used syringes, needles and containers.

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

6. **FURTHER INFORMATION**

**What Human Varicella-Zoster Immunoglobulin contains**

The active substance is immunoglobulin containing a high concentration of antibodies to varicella-zoster virus. The other ingredients are: glycine, sodium chloride, sodium acetate and sodium hydroxide.

**What Human Varicella-Zoster Immunoglobulin looks like and the contents of the pack**

Human Varicella-Zoster Immunoglobulin is a clear to slightly cloudy, colourless to pale yellow sterile solution, available as single dose glass vials containing 250 mg.

These vials are closed with a synthetic rubber stopper, held on by an aluminium ring and flip off cover.

**Marketing Authorisation Holder and manufacturer**

Bi Products Laboratory, Dagger Lane, Elstree, Hertfordshire, WD 6B, United Kingdom

**Marketing Authorisation Number**

PL 0801/0013

This leaflet was last approved in October 2005

For further information 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

February 2009

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Colours: Black

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BPL 4 Products Laboratory