

Package leaflet: Information for the patient
Human Varicella-Zoster Immunoglobulin 100 IU/ml solution for injection

human varicella-zoster immunoglobulin

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or healthcare professional.
- This medicine will be administered for you by your doctor, nurse or healthcare professional.
- If you get any side effects, talk to your doctor, nurse or healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Human Varicella-Zoster Immunoglobulin is and what it is used for
2. What you need to know before you are given Human Varicella-Zoster Immunoglobulin
3. How you are given Human Varicella-Zoster Immunoglobulin
4. Possible side effects
5. How to store Human Varicella-Zoster Immunoglobulin
6. Contents of the pack and other information

1. What Human Varicella-Zoster Immunoglobulin is and what it is used for

This medicine is a solution containing varicella-zoster immunoglobulin (antibodies). It is prepared from blood plasma from screened donors.

It is used to protect you against infection by the varicella-zoster virus (VZV), a virus which causes chickenpox (varicella) and shingles (herpes zoster), in the following at risk groups exposed to the virus:

- newborn babies whose mothers develop chickenpox (varicella) within 7 days before and 7 days after their baby's birth.
- pregnant women with no antibodies to chickenpox or shingles especially up to about 30 weeks of pregnancy.
- newborn babies whose mothers have never had chickenpox and/or are not immune.
- premature infants born before 28 weeks of pregnancy, or newborns with a low birth weight.
- adults and children who have never had chickenpox (varicella) and/or are not immune and their ability to fight infection (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 catch infections such as chicken pox or shingles, unless they are receiving other types of regular antibody (immunoglobulin) treatment.

Your doctor will explain further why this medicine has been given to you.

2. What you need to know before you are given Human Varicella-Zoster Immunoglobulin

Do not use Human Varicella-Zoster Immunoglobulin if you are:

- **allergic** to human immunoglobulins
- **allergic** to any of the ingredients in this product (listed in Section 6).

Warnings and precautions

Talk to your doctor, nurse or healthcare professional before you are given Human Varicella-Zoster Immunoglobulin

- True allergic reactions to this product are rare, when it is injected into the muscle as directed. However, even if you have had this medicine before, you could still have a reaction. In the case of an allergic reaction, urgent medical attention is needed (see also section 4 'Possible side effects').
- If you are lacking immunoglobulin A (IgA deficient) you might develop antibodies to IgA, although this is not common. If you know you already have antibodies to IgA, tell your doctor, nurse or healthcare professional before your injection.
- If you suffer from high blood pressure, diabetes, a history of blood clots or problems with your veins or arteries, or a blood/blood related disorder, tell your doctor, nurse or healthcare professional before this medicine is injected.
- If you have had any vaccinations recently or know you are about to have any vaccinations tell your doctor, nurse or healthcare professional.
- Immunoglobulins may increase the risk of having a blood clot.
- If you develop pain, swelling and unusual warmth of a limb, sudden shortness of breath and chest pain worsening on deep breathing, numbness or weakness on one side, difficulty with speaking or confusion, contact your doctor or nurse immediately as these symptoms may indicate that you have a blood clot.
- Tell your doctor, nurse or healthcare professional if you are having any blood tests. This product will raise the level of various antibodies in your blood for several weeks. If you require a blood test during this period, tell your doctor, nurse or healthcare professional when you last had this product injected as misleading positive results may occur with certain tests.

Viral Safety

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 viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis A (HAV) and parvovirus B19 viruses.

Immunoglobulins have not been associated with HAV 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 medicine are recorded in order to maintain a record of the batches used.

Other medicines and Human Varicella-Zoster Immunoglobulin

Tell your doctor, nurse or healthcare professional if you are taking, have recently taken or might take any other medicines.

Vaccinations

Besides Human Varicella-Zoster antibodies, Human Varicella-Zoster Immunoglobulin provides you with a range of other antibodies. These antibodies will interfere with the response to some vaccines, especially MMR (measles, mumps and rubella) and varicella (chickenpox) vaccines. Such vaccinations should be given at least three weeks before Human Varicella-Zoster Immunoglobulin or not until three months after. In the case of the MMR vaccine, at least 5 months should pass before Human Varicella-Zoster Immunoglobulin is administered. Human Varicella-Zoster Immunoglobulin is unlikely to contain an antibody to yellow fever; so this vaccine can be given whenever needed.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Human Varicella-Zoster Immunoglobulin has no influence on the ability to drive and use machines.

Human Varicella-Zoster Immunoglobulin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How you are given Human Varicella-Zoster Immunoglobulin

This medicine will be given to you by your doctor, nurse or healthcare professional by injection into a muscle. Your doctor, nurse or healthcare professional will decide how much Human Varicella-Zoster Immunoglobulin you should receive.

This medicine must not be injected into the vein since it may cause a severe reaction if given in this way. Injections must be given to you by your doctor, nurse or healthcare professional into a muscle.

Large doses (over 5 ml) will be injected into different parts of the body.

No other medicines or fluids should be added to this product as their effects on the product have not been established.

If you receive more Human Varicella-Zoster Immunoglobulin than you should

If you are given more Human Varicella-Zoster Immunoglobulin than recommended, your doctor, nurse or healthcare professional may carry out some blood tests. It is not known what effects an overdose would have.

If you have any further questions on the use of this medicine, ask your doctor, nurse or healthcare professional.

4. Possible side effects

As with all medicines, Human Varicella-Zoster Immunoglobulin may cause side effects, although not everybody gets them.

If you feel unwell, tell your doctor, nurse or healthcare professional immediately. Side effects may occur even if you have previously been given human immunoglobulins and tolerated them well.

On rare occasions, (may affect up to 1 in 1,000 people) you may experience a strong allergic reaction or a sudden drop in blood pressure.

- Tell your doctor, nurse or healthcare professional immediately if you find it difficult to breathe, if you feel dizzy and faint or if you develop swellings and a red itchy rash. You may need additional treatment to correct your symptoms.

There may be some short-term discomfort at the site of injection such as swelling, soreness, warmth, redness, itching, bruising, or hardening of the skin.

The following side effects have been reported with Human Varicella-Zoster Immunoglobulin:

Not known: frequency cannot be estimated from the available data.

- allergic reaction
- low blood pressure
- feeling sick (nausea), being sick (vomiting)
- back pain
- fever
- chills
- joint pains
- headache
- dizziness
- heart beating very fast (tachycardia)
- skin rash, reddening skin, itchy skin

- joint pains

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Human Varicella-Zoster Immunoglobulin

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of the month.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Short periods (up to 1 week) of storage at room temperature (25°C) will not damage the product.

Keep the vial in the outer carton in order to protect from light.

Do not use the medicine if you notice the solution is cloudy or has deposits.

Disposal

Your doctor, nurse or healthcare professional will dispose of any solution that remains, along with used syringes, needles and containers.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Human Varicella-Zoster Immunoglobulin contains:

- The active substance is human varicella-zoster immunoglobulin.
 - The other ingredients are: sodium chloride, glycine, sodium acetate trihydrate, hydrochloric acid (for pH adjustment) and sodium hydroxide (for pH adjustment).
- Each ml of solution contains at least 100 IU of human varicella-zoster immunoglobulin. The volume required to give the stated dose is printed on the vial label.

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

Human Varicella-Zoster Immunoglobulin is a clear to slightly yellow solution in a clear glass container with a closure to prevent tampering. Do not use solutions that are cloudy or have deposits.

Pack Size

Human Varicella-Zoster Immunoglobulin 100 IU/ml solution for injection
1 x 250 mg vial

Marketing Authorisation Holder

Bio Products Laboratory Ltd, Dagger Lane, Elstree, WD6 3BX, Hertfordshire, United Kingdom.

Manufacturer

Bio Products Laboratory Ltd, Dagger Lane, Elstree, WD6 3BX, Borehamwood, United Kingdom.

For any information about this medicine, please contact the Marketing Authorisation Holder.
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This leaflet was last revised in December 2021