Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

Vazigam® IM, 200 IU (100 IU/ml), solution for injection

Human varicella-zoster immunoglobulin

Sugar free

Read all of this leaflet carefully before you are given Vazigam IM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Vazigam IM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What Vazigam IM is and what it is used for

What Vazigam IM is

Vazigam IM is a solution for injection that contains proteins isolated from human plasma. These proteins belong to the biological class of medicines called immunoglobulins, also known as antibodies.

Vazigam IM contains the active ingredient human varicella-zoster immunoglobulin, which is a specific antibody that works against the varicella-zoster virus (VZV). VZV is a virus that causes chickenpox or shingles.

It is prepared from human plasma from healthy donors that have a high quantity of these antibodies.

What Vazigam IM is used for

Vazigam IM is used to protect against infection caused by the varicella-zoster virus.

This product is usually given to high risk patients who have been **exposed** to the varicella-zoster virus such as in:

- Newborn babies whose mothers develop chickenpox (varicella) within 7 days before or 7 days after the 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 are 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 weakened by certain medicines such as steroids, anti-cancer medicines or by certain treatments such as radiotherapy or recent stem cell transplantation.
- Adults and children who have a weakened immune system which makes them more likely to have infections such as chickenpox or shingles unless they are receiving other types of regular immunoglobulin treatment

2. What you need to know before you are given Vazigam IM

Vazigam IM should not be administered to you:

- If you are hypersensitive (allergic) to human varicella-zoster immunoglobulin or any of the other ingredients in Vazigam IM (listed in section 6).
- If you are hypersensitive to human immunoglobulins.
- If you are immune to the varicella-zoster virus.

Your doctor will decide if you should be given this medicine in this case.

Warnings and precautions

Vazigam IM must not be administered into a vein.

It is not indicated for the treatment of chickenpox or shingles, or for the prevention of disseminated zoster

Tell your doctor or health care provider before being given the injection:

- If you have had a severe allergic reaction to plasma products.
- If you are suffering from any bleeding disorders which interfere with clotting.
- If you have specifically low levels of immunoglobulin A (IgA) as the small amounts of IgA in this preparation may cause an allergic reaction the next time you are given this medicine.

Your doctor will decide if you should be given this medicine in these cases.

Special care should be taken with Vazigam IM:

- True hypersensitivity reactions are rare but allergic type reactions may occur. Tell your doctor or health care provider immediately in case of suspected allergy or serious allergic (anaphylactic) reactions. Your doctor will monitor you closely and will have medication available to treat you if there are any signs of an allergic reaction to Vazigam IM.
- If you are going for a blood test, as this medicine may lead to misleading results. Tell your health care provider if this is the case.

Virus safety

Human varicella-zoster immunoglobulin is prepared from human plasma.

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 (HBV) and hepatitis C virus (HCV).

The measures taken may be of limited value against non-enveloped viruses such as hepatitis A virus and 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.

Traceability

It is strongly recommended that when you receive a dose of Vazigam IM, the name and batch number of the product are recorded in order to maintain a record of the batch used.

Please speak to your health care provider should you require additional information in this regard.

Other medicines and Vazigam IM:

Vazigam IM should not be mixed with other medicines for injection when being given to you.

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines)

Vaccinations

Human varicella-zoster immunoglobulin (antibodies) may interfere with the response to some live virus vaccines, especially measles, mumps, rubella and varicella (chickenpox) vaccines. These vaccines should not be given for 3 months after you were last given Vazigam IM, as the effectiveness of such vaccinations may be reduced.

Vazigam IM with food and drink:

Vazigam IM is injected directly into the muscle and is not affected by food or drink.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

Driving and using machines

You may experience dizziness and other side effects when you receive Vazigam IM.

It is not always possible to predict to what extent Vazigam IM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which Vazigam IM affects you.

3. How to receive Vazigam IM

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself Vazigam IM. It will be given to you by a person who is qualified to do so.

Vazigam IM is for intramuscular use only must never be injected into a vein due to the risk of shock.

It must be injected slowly into a large muscle (such as the upper arm in adults and the side of the thigh in children).

Doses:

At least 15 IU/kg body weight should be given as soon as possible but not more than 4 days after contact with a person who has chickenpox or shingles.

As a guide, the following alternate doses can be used:

0 to 5 years old: 2 ml

6 to 10 years old: 4 ml

11 to 14 years old: 5 ml

15 years and older: 6 ml

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.

If you receive more Vazigam IM than you should:

Your dosage is calculated by your doctor but if you feel unwell after being given this medicine, you should consult your doctor.

Since a health care provider will administer Vazigam IM he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you missed a dose of Vazigam IM

Since a health care provider will administer Vazigam IM, it is unlikely that the dose will be missed.

4. Possible side effects

Vazigam IM can have side effects.

Not all side effects reported for Vazigam IM are included in this leaflet. Should your general health worsen or if you experience any untoward effects after receiving Vazigam IM, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Allergic reaction
- Faintness

These are all very serious side effects. If you have them, you may have had a serious reaction to Vazigam IM. You may need urgent medical attention or hospitalization.

Tell your doctor if you notice any of the following side effects with unknown frequency:

- Headache
- Flushing
- Nausea
- Skin reactions
- Back pain
- Administration site reaction or injection site pain
- Fever
- Chills

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (https://primaryreporting.who-umc.org/ZA) found on SAHPRA website or to National Bioproducts Institute NPC via the email address

Pharmacovigilance@nbisa.org.za. By reporting side effects, you can help provide more information on the safety of Vazigam IM.

5. How to store Vazigam IM

Store all medicines out of reach of children.

- Store between 2 °C and 8 °C (in a refrigerator).
- Do not freeze.
- Protect from light.
- Keep the ampoule in the outer carton until required for use.
- Do not use after the expiry date stated on the label.

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, according to correct procedures. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Vazigam IM contains

- The active substance is a sterile solution of 200 IU (100 IU/ ml) human varicella-zoster immunoglobulin (antibodies)
- The other ingredients are glycine, sodium chloride, sodium hydroxide, hydrochloric acid, human hepatitis B immunoglobulin, human albumin, human normal immunoglobulin and water for injections.
- Vazigam IM does not contain any preservatives.

What Vazigam IM looks like and contents of the pack

Vazigam IM is a solution for injection.

The sterile solution is a clear liquid, with a slightly turbid/cloudy appearance, which is almost colourless or pale yellow to light brown.

Vazigam IM is packed in a sterile, clear, colourless, 2 ml glass ampoule marked with a brown ring.

Holder of Certificate of Registration

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