Package leaflet: Information for the user

Panzyga, 100 mg/ml solution for infusion
Human Normal Immunoglobulin (IVIg)

Read all of this leaflet carefully before you start using 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Panzyga is and what it is used for

What Panzyga is
Panzyga is a human normal immunoglobulin (IgG) solution (i.e. solution of human antibodies) for intravenous administration (i.e. infusion into a vein). Immunoglobulins are normal constituents of the human blood and support the immune defense of your body. Panzyga contains all IgG which are present in the human blood of healthy people. Adequate doses of Panzyga may restore abnormally low IgG levels to the normal range.
Panzyga has a broad spectrum of antibodies against various infectious agents.

What Panzyga is used for
Panzyga is used as replacement therapy in children and adolescents (0-18 years), and adults in different groups of patients:

- Patients with inborn deficiency of antibodies (primary immunodeficiency syndromes, such as: congenital agammaglobulinaemia and hypogammaglobulinaemia, common variable immunodeficiency, severe combined immunodeficiencies)
- Patients with an acquired deficiency of antibodies (secondary immunodeficiency) due to specific diseases and/or treatments and experiencing severe or recurrent infections

Panzyga can be further used in the treatment of the following autoimmune disorders (immunomodulation):

- In patients with immune thrombocytopenia (ITP), a condition where the platelets get destroyed and are therefore reduced in number, and who have a high risk of bleeding or need to correct the platelet count prior to surgery
- In patients with Kawasaki disease, a condition that leads to inflammation of various organs
- In patients with Guillain Barré syndrome, a condition that leads to inflammation of certain parts of the nervous system
- In patients with chronic inflammatory demyelinating polyneuropathy (CIDP), a disease that leads to chronic inflammation of the peripheral parts of the nervous system which causes muscle weakness and/or numbness mainly in the legs and arms.

- In patients with multifocal motor neuropathy (MMN), a condition that is characterized by slow progressive asymmetrical weakness of limbs without sensory loss

2. What you need to know before you use Panzyga

Do NOT use Panzyga:

- if you are allergic to human normal immunoglobulin or any of the other ingredients contained in Panzyga (listed in section 6).
- if you have a deficiency of immunoglobulin A (IgA deficiency) and if you have developed antibodies against immunoglobulins of the type IgA.

Warnings and precautions

Talk to your doctor or pharmacist before using Panzyga.

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

Certain adverse reactions may occur more frequently:

- in case of high rate of infusion
- when you receive Panzyga for the first time or, in rare cases, when there has been a long interval since the previous infusion.
- when you have an untreated infection or an underlying chronic inflammation

In the case of an adverse reaction, your doctor will either reduce the rate of administration or stop the infusion. The treatment of the adverse event required will depend on the nature and severity of the adverse event.

Circumstances and conditions increasing the risk of having side effects

- Thromboembolic events such as heart attack, stroke, and obstructions of a deep vein for example in the calves or of a blood vessel in the lung may occur very rarely after administration of Panzyga. These types of events occur more commonly in patients with risk factors, such as obesity, advanced age, high blood pressure, diabetes, previous occurrences of such events, prolonged periods of immobilisations, and intake of certain hormones (e.g. the pill). Ensure a balanced fluid intake; moreover Panzyga should be administered as slowly as possible.
- If you had kidney problems in the past or if you have certain risk factors like diabetes, overweight, or age over 65, Panzyga should be administered as slowly as possible because cases of acute kidney failure have been reported in patients with such risk factors. Tell your doctor, even when any of the above-mentioned circumstances had happened to you in the past.
- Patients with blood group A, B or AB as well as patients with certain inflammatory conditions have a higher risk of red blood cells being destroyed by the administered immunoglobulins (called haemolysis).

When may slowing or stopping the infusion be required?

- Strong headaches and neck stiffness may occur several hours to 2 days following Panzyga treatment.
- Allergic reactions are rare, but can induce an anaphylactic shock, even in patients who had tolerated the previous treatments. A sudden fall in blood pressure or shock may be consequences of an anaphylactic reaction.
- In very rare cases transfusion-related acute lung injury (TRALI) can occur after receiving immunoglobulins including Panyzga. This will lead to non-heart related accumulation of fluid in the air spaces of the lungs. You will recognize TRALI by severe difficulty in breathing,

normal heart function and increased body temperature (fever). Symptoms typically appear within 1 to 6 hours after receiving treatment.

Tell your doctor or healthcare professional immediately if you notice any of the above mentioned symptoms during or after the infusion of Panzyga. He or she will decide whether to decrease the infusion rate or to stop the infusion completely or if further measures are necessary.

- Sometimes immunoglobulin solutions such as Panzyga can trigger a decrease in the number of white blood cells. Normally this condition resolves spontaneously within 1-2 weeks.

Effects on blood tests

Panzyga contains a wide variety of different antibodies, some of which can affect blood tests. If you have a blood test after receiving Panzyga, please inform the person taking your blood or your doctor that you have received a human normal immunoglobulin solution.

Virus 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
- testing of each donation and pools of plasma for signs of virus/infections
- steps included by the manufacturers 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 encapsulated viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus and for the non-encapsulated 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.

Children and adolescents

There are no specific or additional warnings or precautions applicable for children and adolescents.

Other medicines and Panzyga

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, or if you have received a vaccination in the last three months.

Panzyga may impair the effect of live attenuated virus vaccines such as

- measles
- rubella
- mumps
- varicella.

After administration of this product, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to 1 year.

Panzyga, 100 mg/ml with food, drink and alcohol

No effects have been observed. While using Panzyga, 100 mg/ml adequate hydration before infusion should be taken into account.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist if you can get or continue with Panzyga.

The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials and therefore should only be given with caution to pregnant women and breast-feeding mothers. Immunoglobulin preparations have been shown to cross the placenta, increasingly during the third trimester. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.

Immunoglobulins are excreted into human milk. No negative effects on the breastfed newborns/infants are anticipated

Driving and using machines

Panzyga has no or negligible influence on the ability to drive and use machines. However, patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines

Panzyga contains sodium

This medicinal product contains 69 mg sodium (main component of cooking/table salt) per vial of 100 ml. This is equivalent to 3.45% of the recommended maximum daily dietary intake of sodium for an adult.
To be taken into consideration by patients on a controlled sodium diet.

3. How to use Panzyga

Your doctor will decide if you need Panzyga and at what dose. Panzyga is administered as an intravenous infusion (infusion into a vein) by healthcare personnel. The dose and dosage regimen is dependent on the indication and may need to be individualised for each patient.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Use in children and adolescents

The administration (intravenously) of Panzyga in children and adolescents (0-18 years) does not differ from the administration in adults.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor as soon as possible if you suffer from any of the serious side effects listed below (**all are very rare** and may affect up to 1 in 10,000 infusions). In some cases your doctor may need to interrupt treatment and reduce your dose or stop treatment:

- **Swelling of the face, tongue and windpipe** that can cause great difficulty in breathing
- **A sudden allergic reaction** with shortness of breath, rash, wheezing and drop of blood pressure
- **Stroke** that may cause weakness and / or loss of sensation down one side of the body
- **Heart attack** causing chest pain
- **Blood clot** causing pain and swelling of limbs
- **Blood clot in lung** causing chest pain and breathlessness
- **Anaemia** causing shortness of breath or looking pale

- **Severe kidney disorder** that may cause you to not pass urine
- A **lung condition** referred to as transfusion-related acute lung injury (TRALI) causing difficulty in breathing, bluish skin, fever, a decrease in blood pressure

If you experience any of the symptoms above, contact your doctor as soon as possible.

The following other side effects have also been reported:

Common side effects (may affect up to 1 in 10 infusions):
Headache, nausea, fever

Uncommon side effects (may affect up to 1 in 100 infusions):
Skin rash, back pain, chest pain, chills, dizziness, feeling tired, cough, vomiting, belly pain, diarrhoea, joint pain, muscle pain, infusion site itching, rash, neck pain, pain in arm or leg, reduced sense of touch or sensation, reduction of red blood cells, reduction of white blood cells, aseptic meningitis (see also section Warnings and Precautions), eye itching, fast beating of the heart, increased blood pressure, ear pain, stiffness, feeling cold, feeling hot, feeling unwell, shiver, numbness, changes in blood tests that report on how the liver is working.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Panzyga

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

Do not use this medicine after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of the month.

Store in a refrigerator (2°C – 8°C). Keep the container in the outer carton in order to protect from light. Do not freeze.

The product may be removed from the refrigerator for a period of 12 months (without exceeding the expiry date) and stored above +8°C and below +25°C. At the end of this period, the product should not be refrigerated again and should be disposed of. The date at which the product was taken out of the refrigerator should be recorded on the outer carton.

Do not use this medicine if you notice that the solution is cloudy, has deposits or is coloured intensively.

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 to protect the environment.

6. Contents of the pack and other information

What Panzyga contains

- The active substance is human normal immunoglobulin (human antibodies). Panzyga contains 100 mg/ml human protein of which at least 95% is immunoglobulin G (IgG).
- The other ingredients are glycine and water for injections.

What Panzyga looks like and contents of the pack

Panzyga is a solution for infusion and is available in vials (1 g/10 ml, 2.5 g/25 ml) or bottles (5 g/50 ml, 6 g/60 ml, 10 g/100 ml, 20 g/200 ml, 30 g/300 ml).

Pack sizes:

1 vial (1 g/10 ml; 2.5 g/25 ml)
1 bottle (5 g/50 ml; 6 g/60 ml; 10 g/100 ml; 20 g/200 ml; 30 g/300 ml)
3 bottles (10 g/100 ml; 20 g/200 ml)

The solution is clear or slightly opalescent, colourless or slightly yellow.

Not all pack sizes may be marketed.

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This medicinal product is authorised in the member states of the EEA under the following names:

Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom:	Panzyga®
Italy:	Globiga®

This leaflet was last approved in 09/2023.

The following information is intended for medical or healthcare professionals only:

- The product should be brought to room or body temperature before use.
- The solution should be clear to slightly opalescent and colourless to slightly yellow.
- Solutions that are cloudy or have deposits should not be used.
- Any unused product or waste material should be disposed of in accordance with local requirements.

- This medicinal product should not be mixed with other medicinal products.
- In order to infuse any product that may remain in the infusion tubing at the end of the infusion the tubing may be flushed with either 0.9% (9 mg/ml) saline or 5% (50 mg/ml) dextrose solution.