READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PANZYGA®
Immunoglobulin Intravenous (Human)

Read this carefully before you start taking *Panzyga®* and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about *Panzyga®*.

Serious Warnings and Precautions

- Thromboembolic events such as heart attack, stroke, and obstructions of a deep vein e.g. in the calves or of a blood vessel in the lung (pulmonary embolism) may occur with administration of human immunoglobulin intravenous (IVIG) products.
- Thromboembolic events occur more commonly in patients with pre-existing risk factors for thromboembolism receiving IVIG products.

  In general the risk factors for thromboembolic events include: obesity; advance age; hypertension; diabetes mellitus; previous events of heart attack, stroke, and obstructions of a deep vein etc.; prolonged periods of immobilisation; intake of certain hormones (e.g. the pill).
- Thrombosis may occur even in the absence of known risk factors.

What is *Panzyga®* used for?

1) *Panzyga®* is used to treat adults and children:
   - Who are either born with (PID) or develop (SID) not enough protective proteins (Immunoglobulins) in their blood to defend against infections.

2) *Panzyga®* is used to treat adults:
   - Who do not have enough blood platelets and who are at high risk of bleeding (immune thrombocytopenic purpura, ITP).
   - Who suffer from moderate to severe Guillain-Barré Syndrome (GBS).

How does *Panzyga®* work?

Panzyga® is used as antibody replacement therapy, in people who have low levels of these infection-fighting proteins. By replacing these important antibodies, *Panzyga®* helps make people better able to avoid infections and fight them when they do occur.

How *Panzyga®* works in immune thrombocytopenic purpura is unknown, but it is believed to block platelet removal from the bloodstream. The mechanism of action in ITP and GBS is not fully understood, but includes modulatory effects of the immune system.

What are the ingredients in *Panzyga*®?

Medicinal ingredients: Immunoglobulin Intravenous (Human)
Non-medicinal ingredients: Glycine, Water for Injections

***Panzyga*® comes in the following dosage forms:**

Panzyga® is a 100 mg/mL solution for intravenous infusion and comes in the following dosage forms:

Fill Size	Grams IgG
10 mL	1 g
25 mL	2.5 g
50 mL	5 g
100 mL	10 g
200 mL	20 g
300 mL	30 g

Do not use *Panzyga*® if:

- You have a history of severe allergic reactions to immunoglobulin treatment.
- You have a condition known as selective IgA deficiency.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take *Panzyga*®. Talk about any health conditions or problems you may have, including:

- If you have a history of allergic or other reactions to immunoglobulins or to any of the ingredients.
- If you have a history of heart disease, problems with your circulation or have had blood clots.
- If you have a history of migraine.
- If you have a history of kidney disease or diabetes.
- If you are pregnant or think that you are pregnant or if you are nursing.
- If you have recently been vaccinated.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with *Panzyga*®:

Panzyga® may reduce the effect of certain virus vaccines, such as measles, mumps and rubella. Inform the immunizing physician of recent treatments with *Panzyga*® so appropriate precautions can be taken.

Panzyga® should not be mixed with other 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.

How to take *Panzyga*®:

Panzyga® is injected into a vein. It should not be used if it looks cloudy or is leaking. It should be warmed up to room or body temperature before use. Discard any remaining contents after use. Do not use the product after its expiry date (printed on the bottle).

Usual dose:

Your doctor will determine the dose(s) of *Panzyga*®.

The usual dose of *Panzyga*® for patients with Primary or Secondary Immune Deficiency is 200 to 800 mg/kg body weight, every 3 to 4 weeks. Doses may be adjusted over time to achieve the desired clinical response and serum IgG levels.

The usual dose for patients with Immune Thrombocytopenic Purpura is 1g/kg body weight for 2 consecutive days.

The usual starting dose of *Panzyga*® for patients with Guillain-Barré Syndrome is 2 g/kg body weight given in divided doses over 2 to 5 consecutive days.

Overdose:

Overdose may lead to fluid overload, particularly in the elderly and in patients with kidney problems.

If you think you have taken too much *Panzyga*®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

A missed dose should be given as soon as possible.

What are possible side effects from using *Panzyga*®?

These are not all the possible side effects you may feel when taking *Panzyga*®. If you experience any side effects not listed here, contact your healthcare professional.

The following symptoms are common:

- Headache
- Nausea
- Fever

The following symptoms are uncommonly observed:

- Dizziness
- Chills
- Eye itching
- Ear pain
- Fast heart rate
- Increase in blood pressure
- Cough
- Vomiting
- Belly pain or discomfort
- Rash
- Joint or muscle pain
- Chest pain
- Feeling cold
- Physical weakness
- Fatigue
- Changes in liver function parameters (lab test)
- Drop in white or red blood cells (lab test)

If any of the above listed symptoms occur, are severe or if they worry you, talk to your doctor or pharmacist.

Panzyga® has been manufactured with specific steps to reduce the risk of complications due to formation of blood clots. However, patients with known risk factors should be well hydrated by taking adequate fluids and *Panzyga*® may be injected at a slower speed.

This is not a complete list of side effects. For any unexpected effects while taking *Panzyga*®, contact your doctor or pharmacist.
If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect; write out website
- By calling 1-866-234-2345 (toll-free);
- By completing a Patient Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

    Postage paid labels and the Patient Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store refrigerated (+2 °C to +8 °C) for up to 36 months. Within this shelf-life the product may be stored up to 12 months at ≤ 25°C. After the storage at ≤ 25°C the product must be used or discarded.
Warm up to room or body temperature before use. Do not freeze. Protect from light. Discard any remaining contents after use. Do not use after expiry date.

Keep out of reach and sight of children.

If you want more information about *Panzyga*®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website http://www.octapharma.ca, or by calling 1-888-438-0488.

This leaflet was prepared by Octapharma Pharmazeutika Produktionsges.m.b.H

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