

#### SELECTED SAFETY INFORMATION

#### WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

See full prescribing information for complete BOXED WARNING

- Thrombosis may occur with immune globulin intravenous (IGIV) products, including PANZYGA. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.
- Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur
  with the administration of IGIV products in predisposed patients. Renal dysfunction
  and acute renal failure occur more commonly in patients receiving IGIV products
  containing sucrose. PANZYGA does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer PANZYGA at the minimum infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.



#### What is CIDP?

## CIDP, or chronic inflammatory demyelinating polyneuropathy, is a rare medical condition that can be difficult to diagnose.

In CIDP, the immune system attacks healthy tissue, affecting the nerves in a person's arms and legs.

CIDP is most commonly experienced as weakness in the arms and legs, and may be accompanied by a prickling sensation and numbness. Symptoms can happen in waves, coming and going over time, or progress consistently.

#### **Symptoms of CIDP may include:**



Loss of reflexes



Prickling sensation & numbness



Difficulty with fine motor skills



Weakness in arms & legs



Loss of coordination & difficulty walking/standing up



**Fatigue** 

#### **After diagnosis**

Your care team will work together to treat your CIDP. This may include neurologists, neuromuscular specialists, neurophysiologists, pharmacists, and nurses.

#### Your care team may choose from these available treatments

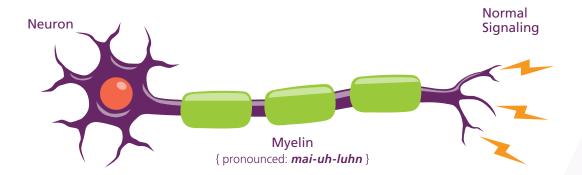
- Intravenous immunoglobulin (IVIg): Adds new antibodies to the body to block the attacking antibodies
- Corticosteroids: Help reduce inflammation and relieve symptoms
- Plasma exchange: Removes attacking antibodies from the body
- Immunosuppressants: Minimize the immune response



#### What causes CIDP?

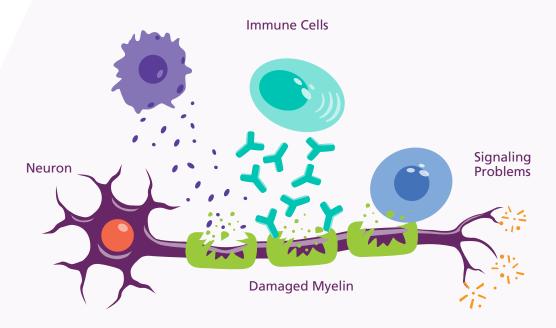
#### In a healthy body

Neurons deliver messages between the brain and the rest of the body to perform actions like picking up a cup or taking a step. Myelin is a protective layer around a neuron—like insulation around a wire—that helps messages get to their destinations.



#### When someone has CIDP

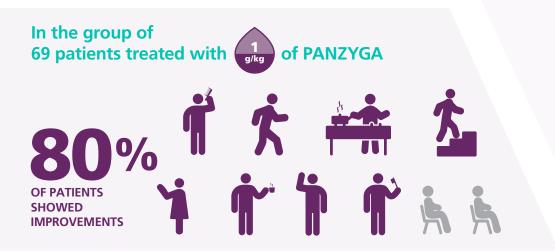
The immune system, which usually recognizes foreign germs in the body and fights them off, starts to think the neurons in a person's limbs are foreign and attacks. The immune system damages the protective myelin coating, causing the messages neurons deliver to be slowed or lost.



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# In a clinical study, PANZYGA improved limb disability and impairment symptoms related to CIDP

PANZYGA is an IVIg therapy that was studied in patients with CIDP. Patients in the study were divided into groups, each receiving a different dose of PANZYGA. Response to treatment was dependent on dose: the higher the dose, the more people responded.





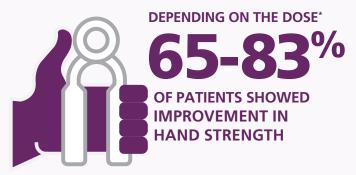
PANZYGA was also tested at a higher dose of 2 g/kg in 36 patients. 92% of patients who received the 2 g/kg dose of PANZYGA improved\*

Response to treatment was an improvement in a patient's score based on an examination that measures arm and leg mobility.

<sup>\*</sup>Dose-dependent increases in headache were observed in 2 g/kg treatment group.

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# Patients in the study also showed improvement in hand strength



\*65% of patients (45 of 69) who took 1 g/kg showed improvement and 83% of patients (30 of 36) who took 2 g/kg showed improvement.

With 2 approved dosing strengths, your doctor has the option to increase or decrease your dose as needed.

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#### Do not use PANZYGA if you:

- Have had a severe allergic reaction to immune globulin or other blood products
- Have a condition called selective (or severe) immunoglobulin A (IgA) deficiency, with antibodies against IgA and a history of hypersensitivity

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# What were the most common side effects of PANZYGA in the clinical study?







Fever: 14%



Skin Irritation: 10%



Increased Blood Pressure: 8%

## Reports of headache were dependent on dose: the higher the dose, the more patients reported

- 24% of patients who received the 2 g/kg dose of PANZYGA reported headache
- 15% of patients who received the 1 g/kg dose of PANZYGA reported headache.



#### **SELECTED SAFETY INFORMATION**

#### What should I know before taking PANZYGA?

- PANZYGA can make vaccines (like measles/mumps/rubella or chickenpox vaccines) work less effectively for you. Before you get any vaccines, tell your healthcare provider that you take PANZYGA
- Decreased kidney function and kidney function failure can occur

Please refer to the Selected Safety Information on pages 18-20 for more information on serious side effects.

Please click <u>here</u> for Full Prescribing Information, including complete BOXED WARNING.

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#### How do you receive PANZYGA?

PANZYGA is administered at home, in a hospital, or at an infusion center by a healthcare professional. They will start your infusion at a slow rate and increase the rate if you tolerate it well.

The healthcare professional will be looking for signs of infusion reactions and may slow or stop your PANZYGA treatment if you experience a severe reaction. Slowing or stopping the infusion may help these symptoms to go away.

#### **Getting ready for your infusion**



Make sure to stay well hydrated the day before and the day of your IVIg therapy, and avoid caffeine and alcohol



Have something with you to help pass the time

#### **During and after your infusion**



Your IVIg therapy will be given as an infusion through a needle inserted into your vein



Your blood pressure and temperature will be checked during treatment



Your infusion time will vary and could take several hours



You can continue with the regular activities of your day, as tolerated



Call your doctor, nurse, or pharmacist with any questions, or if you become worried about side effects

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#### **Dosing options**

In the clinical study, PANZYGA infusions occurred every 3 weeks. After your starting dose, you and your doctor will work together to determine the best dose for your ongoing treatments. This dose can be adjusted as needed.



All doses are split over the course of 2 days

PANZYGA was tested at multiple doses in the clinical study, and patients saw symptom improvement at both the 1 and 2 g/kg doses

#### **SELECTED SAFETY INFORMATION**

What should I know before taking PANZYGA? (continued)

- Severe headache, drowsiness, fever, painful eye movements, or nausea and vomiting can occur
- Elevated blood pressure can occur particularly in patients who have a history of hypertension (high blood pressure)
- If you are elderly, with heart or kidney problems, discuss with your healthcare provider prior to initiating treatment with PANZYGA
- PANZYGA is made from human blood and therefore may have a risk of transmitting infectious agents, including viruses and, theoretically, the variant Creutzfeldt-Jakob disease (CJD) and CJD agent. The production and manufacturing process reduces this risk, but the risk cannot be eliminated

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#### How is PANZYGA made?

#### PANZYGA is made from healthy human plasma

IVIg therapy, like PANZYGA, is made from human plasma, which is collected from the blood of healthy donors in the US. Production of PANZYGA follows strict guidelines to minimize the risk of transmitting infectious agents, such as viruses.

#### **Guidelines include:**

- · Obtaining human plasma from FDA-approved establishments
- Screening plasma donors for prior exposure to certain viruses and other diseases
- Testing the collected plasma to help ensure that it is virus and disease free
- Virus inactivation/removal steps in the manufacturing process



FDA=Food and Drug Administration.

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#### **Support** is available

Your specialty infusion pharmacy may be able to provide you with additional materials about your treatment. Additionally, the following educational resources are available at **Panzygalnfo.com**:



### Co-Pay Program Brochure

Provides details about the PANZYGA Co-Pay Program



#### **Therapy Tracker**

An easy way for you to record your progress and communicate with your healthcare provider



#### What to Expect From Your IVIg Therapy Brochure

A brochure to help you prepare for IVIg therapy

#### Join the PANZYGA Patient Resource Program!

We understand that CIDP can significantly impact your life and we want to help get you started with free patient and caregiver resources sent right to your inbox.

Sign-up at Panzygalnfo.com.



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# Pfizer offers a co-pay assistance program for PANZYGA

For eligible patients prescribed PANZYGA, the Pfizer PANZYGA Co-Pay Program is available through specialty infusion pharmacies. The program provides eligible, commercially insured patients assistance of up to \$5,000\* per calendar year or the cost of patient's co-pay in a 12-month period (whichever is less) for claims received by the program.

#### **Eligibility requirements include:**

- Patients must have commercial insurance to be eligible
- Patients are not eligible if they are enrolled in a state or federally funded insurance program



Contact your specialty infusion pharmacy to see if you are eligible.

\*See terms and conditions at PanzygaInfo.com

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# The Pfizer Pledge Warranty Program\*† for adult patients with CIDP starting PANZYGA

As part of its commitment to patients with CIDP, Pfizer is proud to offer the **Pfizer Pledge Warranty Program\*** for adult **patients with CIDP starting PANZYGA**. With this program, eligible patients can get their out-of-pocket drug costs for PANZYGA refunded. See below to learn more



#### What does the Pfizer Pledge Warranty Program offer?



- With this program, eligible patients can be refunded their out-of-pocket drug costs for up to the first 4 treatments of PANZYGA for chronic inflammatory demyelinating polyneuropathy (CIDP) if the treatment is discontinued by the patient's healthcare provider for clinical reasons
- Per treatment and aggregate maximum refund limits apply. If the patient's commercial
  insurance and/or other payers paid for all or a portion of the cost of PANZYGA, the plan(s)
  can be refunded those costs up to the program maximum limits minus any out-of-pocket
  drug costs paid by the patient



#### Who is eligible for the Pfizer Pledge Warranty Program?

- The Pfizer Pledge Warranty Program is available to adult, cash-paying or commercially insured patients (those with employer-sponsored or private insurance) prescribed PANZYGA for CIDP whose healthcare provider discontinues treatment for clinical reasons before the fifth treatment<sup>†</sup>
- Patients are not eligible for the program if their PANZYGA was covered, in whole or in part, by Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico



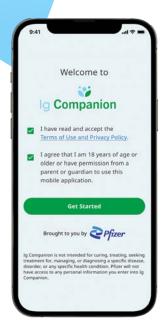
#### How can a patient make a claim?

• For information on the Pfizer Pledge Warranty Program and for access to resources, such as patient claim forms, please visit **Panzygalnfo.com** 



<sup>\*</sup>Not available for residents of Puerto Rico

<sup>&</sup>lt;sup>†</sup>Terms and conditions/eligibility requirements apply. See full terms and conditions at <u>Panzygalnfo.com</u>. <sup>†</sup>Single treatments may be given over 1 or more days.





Pfizer is committed to providing tools and resources to help support patients on Ig therapy

Ig Companion is a free mobile app designed to complement the treatment experience for patients and caregivers and help prepare them for doctor visits

Please click <u>here</u> for Full Prescribing Information, including complete BOXED WARNING.



## Key features of the Ig Companion free mobile app include helping patients:



Navigate through the infusion process



Access educational content



Track, manage, and export infusion information



Set reminders for events



Ig Companion is not intended for curing, treating, seeking treatment for, managing, or diagnosing a specific disease, disorder, or any specific health condition. Pfizer will not have access to any personal information you enter into Ig Companion.

Available for free download from the App Store and Google Play.





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Immune Globulin Intravenous (Human) - ifas 10% Liquid Preparation

#### INDICATIONS AND USAGE

PANZYGA (Immune Globulin Intravenous [Human] – ifas) is indicated for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older, chronic immune thrombocytopenia (cITP) in adults and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

PANZYGA is a liquid medicine for infusion that contains immunoglobulin G (IgG), which are proteins that help fight infection. It is made from human plasma that is donated by healthy people and contains antibodies. For patients with PI, PANZYGA helps replace the missing antibodies in the body. For patients with cITP, PANZYGA helps the body produce more platelets (the blood cells that help blood clot) to control or prevent bleeding. For patients with CIDP, PANZYGA may help improve mobility and hand strength.

PANZYGA is given into a vein (intravenously) in a hospital, infusion center, doctor's office, or at home by a trained healthcare provider (HCP).

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### **SELECTED SAFETY INFORMATION** (continued on next page)

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## SELECTED SAFETY INFORMATION (continued from prior page) What should I know before taking PANZYGA?

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- Decreased kidney function and kidney function failure can occur
- Severe headache, drowsiness, fever, painful eye movements, or nausea and vomiting can occur
- Elevated blood pressure can occur particularly in patients who have a history of hypertension (high blood pressure)
- If you are elderly, with heart or kidney problems, discuss with your healthcare provider prior to initiating treatment with PANZYGA
- PANZYGA is made from human blood and therefore may have a risk of transmitting infectious agents, including viruses and, theoretically, the variant Creutzfeldt-Jakob disease (CJD) and CJD agent. The production and manufacturing process reduces this risk, but the risk cannot be eliminated

# PANZYGA can cause serious side effects. If any of the following problems occur after starting PANZYGA, stop the infusion immediately and contact your HCP or call emergency services:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting, or dizziness. These could be signs of a serious allergic reaction
- Bad headache with nausea, vomiting, stiff neck, fever, drowsiness, painful eye
  movements, and sensitivity to light. These could be signs of irritation and swelling
  of the lining around your brain
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem (decreased kidney function or kidney failure)
- Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot, which could happen in the heart, brain, lungs, or elsewhere in the body

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- **SELECTED SAFETY INFORMATION** (continued from prior page)
  - Brown or red urine, swelling, fatigue, fast heart rate, difficulty breathing, or yellow skin or eyes. These could be signs of a liver or blood problem
  - Chest pain or trouble breathing, or blue lips or extremities. These could be signs of a serious heart or lung problem
  - Fever over 100°F. This could be a sign of an infection
  - Headache, fatigue or confusion, vision problem, chest pain, difficulty breathing, irregular heartbeat, or pounding in your chest, neck, or ears. These could be signs of high blood pressure

Ask your HCP whether you should have rescue medications available, such as antihistamines or epinephrine.

#### What are the possible or reasonably likely side effects for PANZYGA?

The most common side effects that may occur with PANZYGA are:

Headache

• Increased blood pressure

Abdominal pain

Nausea

Dermatitis

Dizziness

Fever

Fatique

Anemia

These are not all the possible side effects. Talk to your HCP about any side effect that bothers you or that does not go away.

Tell your HCP if you are pregnant, or plan to become pregnant, or if you are nursing.

#### Why PANZYGA?

- PANZYGA was tested at multiple doses in the clinical study, and patients saw an improvement in arm and leg mobility and function in both the 1 and 2 g/kg dose groups
- After starting on PANZYGA, you and your doctor will work together to find which ongoing treatment dose works best for you





PANZYGA is an IVIg treatment shown to improve CIDP-related disability and impairment.

> Visit Panzygalnfo.com for more information

Patients should always ask their doctors for medical advice about adverse events.

You may report an adverse event related to Pfizer products by calling 1-800-438-1985 (US only). If you prefer, you may contact the US Food and Drug Administration (FDA) directly. The FDA has established a reporting service known as MedWatch where healthcare professionals and consumers can report problems they suspect may be associated with the drugs and medical devices they prescribe, dispense, or use. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

PANZYGA® is a registered trademark of Octapharma AG.



**Pfizer** octapharma

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Please click <u>here</u> for Full Prescribing Information, including complete BOXED WARNING.

panzyga<sup>®</sup> Immune Globulin Intravenous (Human) - ifas 10% Liquid Preparation