

What Causes CIDP?

PANZYGA **Clinical Data**

> Receiving PANZYGA

How Is PANZYGA Made?

Patient Resources and Programs

lg Companion

Important Safety Information

Why PANZYGA?

panzyga®

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

SELECTED SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE See full prescribing information for complete BOXED WARNING

- hyperviscosity, and cardiovascular risk factors.
- not contain sucrose.
- for hyperviscosity.

For the treatment of adults with chronic inflammatory demyelinating

PANZYGA--Strength to move forward {pronounced: pan-zee-guh}

Not an actual patient.

• 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,

• 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

• 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

polyneuropathy (CIDP) to improve neuromuscular disability and impairment

Co-pay savings have increased for eligible patients. See details inside.







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Why PANZYGA?

What is CIDP?

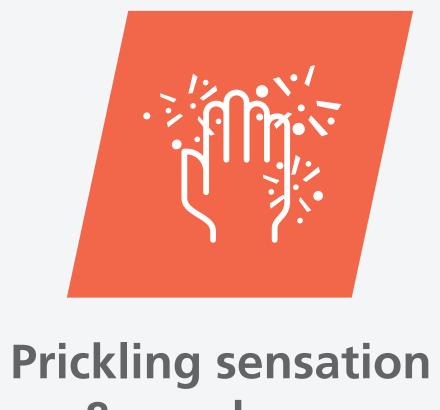
CIDP, or chronic inflammatory demyelinating polyneuropathy, is a rare medical condition that can be difficult to diagnose.

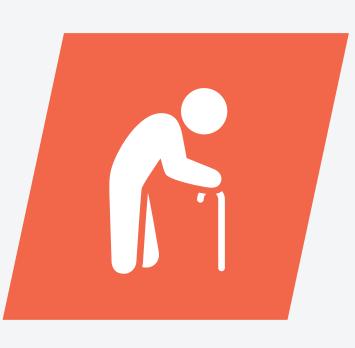
In CIDP, the immune system attacks healthy tissue, affecting the nerves in a person's arms and legs.

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.



Loss of reflexes





Weakness in arms & legs

Symptoms of CIDP may include:

& numbness



Loss of coordination & difficulty walking/standing up



Difficulty with fine motor skills



Pain & fatigue



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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 immunoglobin (IVIg): Adds new antibodies to the body to block the attacking antibodies. PANZYGA is an IVIg therapy
- Corticosteroids: Help reduce inflammation and relieve symptoms
- Plasma exchange: Removes attacking antibodies from the body
- Immunosuppressants: Minimize the immune response







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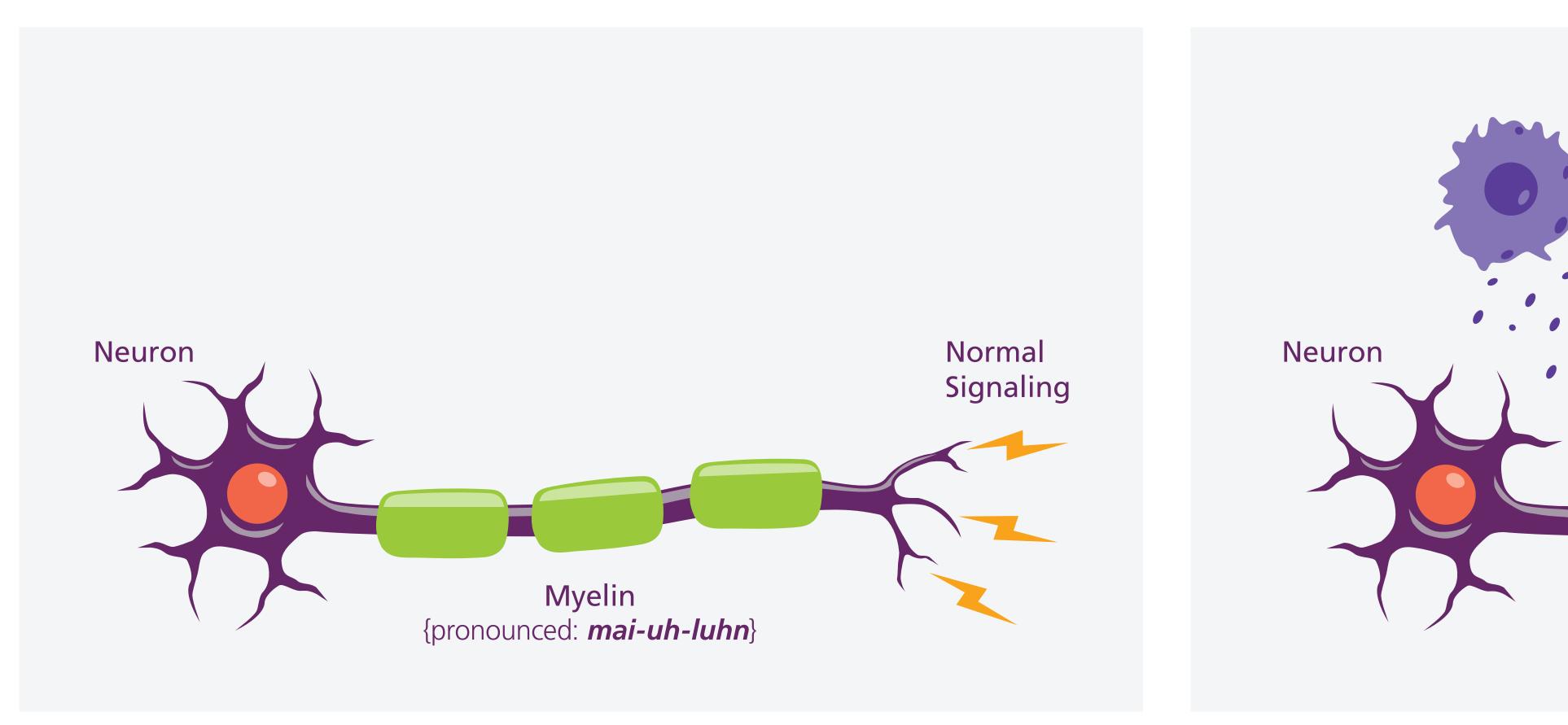
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Why PANZYGA?

What causes CIDP?

In a healthy body

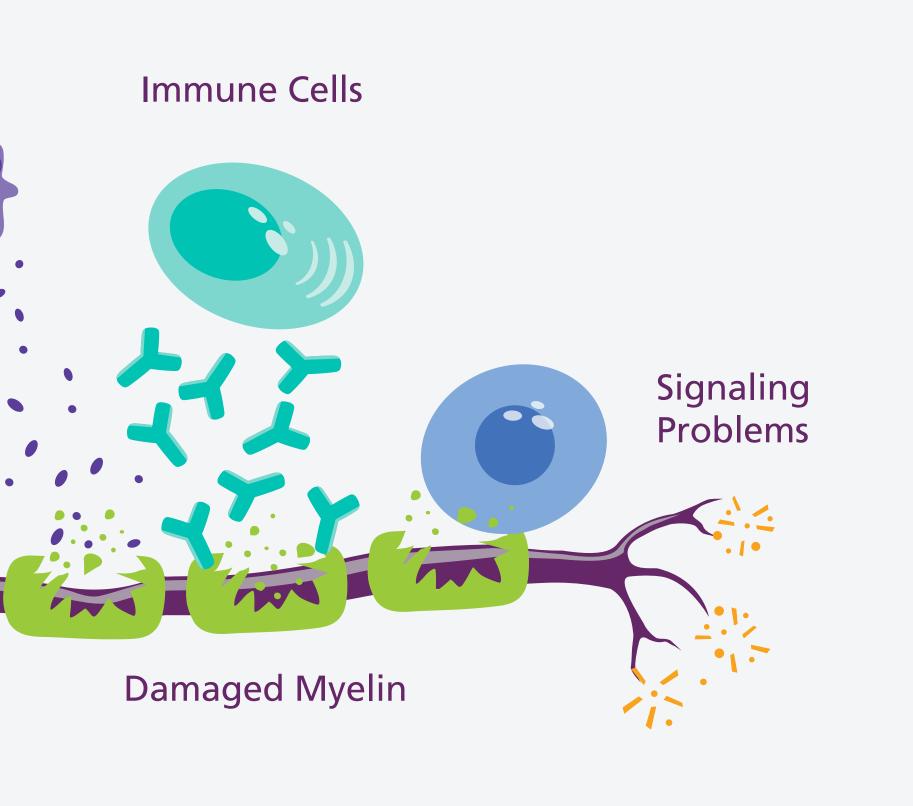
Neurons deliver messages between the brain and the rest of the body to perform actions like picking up a cup or taking a step. Myelin is a protective layer around a neuron—like insulation around a wire—that helps messages get to their destinations.





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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Why PANZYGA?

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

PANZYGA is an IVIg therapy that was studied in adult patients with CIDP. Adult 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.

In the group of

OF PATIENTS SHOWED **IMPROVEMENTS***



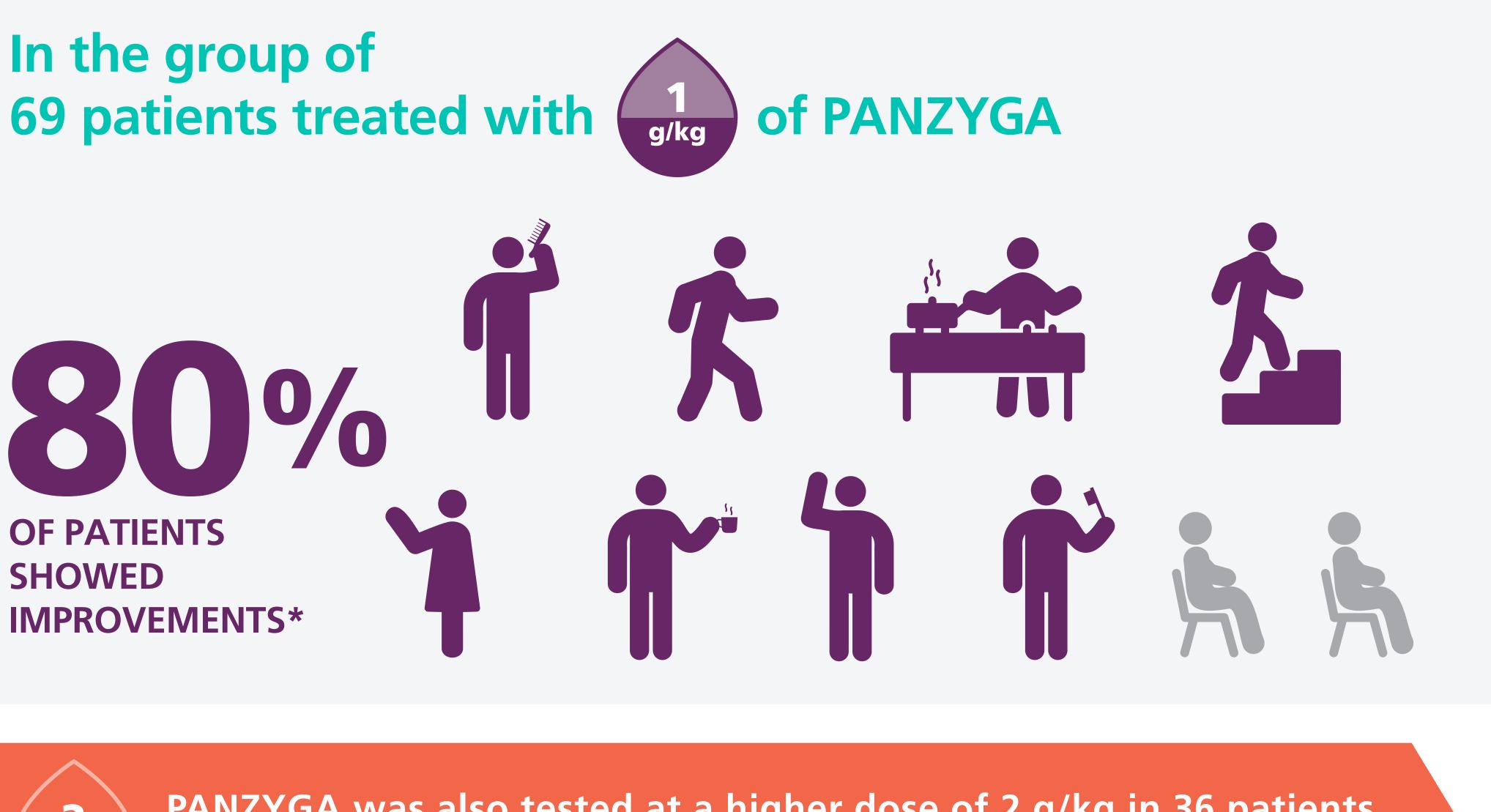
*Response to treatment was an improvement in a patient's score based on an examination that measures arm and leg mobility. ⁺Dose-dependent increases in headache were observed in 2 g/kg treatment group.

SELECTED SAFETY INFORMATION

Do not use PANZYGA if you:

- of hypersensitivity

Please click here for Full Prescribing Information, including complete BOXED WARNING.



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[†]

• 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



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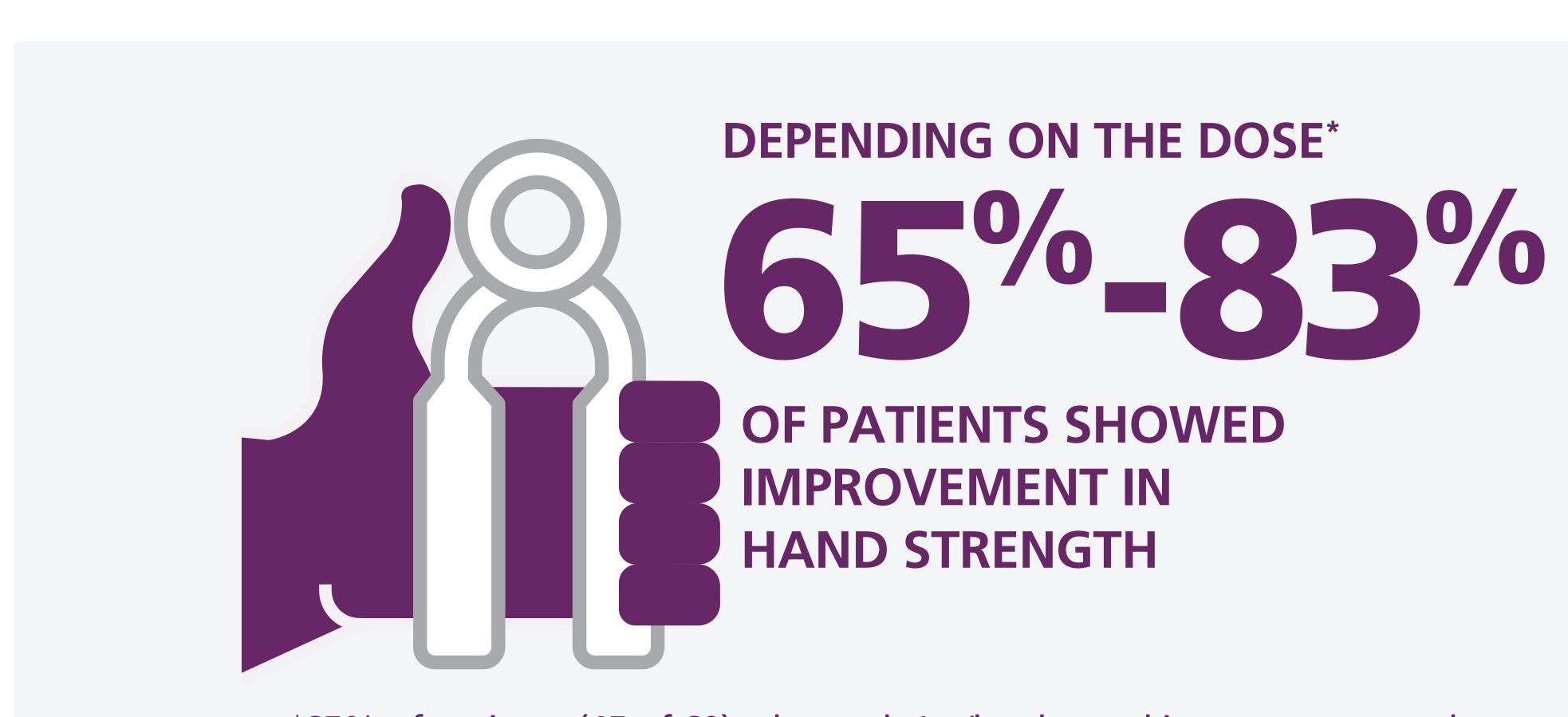
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Why PANZYGA?

Adult patients in the study also showed improvement in hand strength



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

SELECTED SAFETY INFORMATION

What should I know before taking PANZYGA?

- vaccines, tell your healthcare provider that you take PANZYGA
- Decreased kidney function and kidney function failure can occur

*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.

• PANZYGA can make vaccines (like measles/mumps/rubella or chickenpox vaccines) work less effectively for you. Before you get any

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Why PANZYGA?

Adult patients in the study also reported less pain

PATIENTS REPORTED **ON AVERAGE**

*Patient self-reporting of pain was based on an 11-point scale, ranging from 0 (no pain) to 10 (worst possible pain). Patients who received the 1 g/kg dose reported 47% less pain and patients receiving the 2 g/kg dose reported 43% less pain.

SELECTED SAFETY INFORMATION <u>What should I know before taking PANZYGA?</u> (continued)

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



• 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) panzyga® Immune Globulin Intravenous (Human) - ifas



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Why PANZYGA?

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



Headache: 15%

Of all side effects:

79% were mild

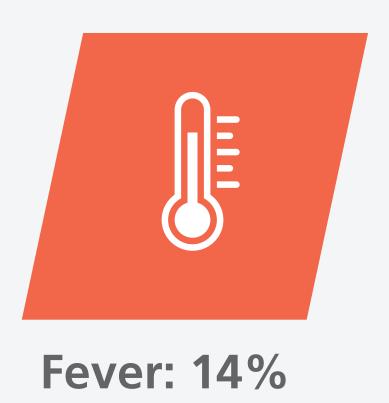
Reports of headache were dependent on dose:

SELECTED SAFETY INFORMATION What should I know before taking PANZYGA? (continued)

- cannot be eliminated

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

The most common side effects of PANZYGA among patients receiving a 0.5 g/kg, 1 g/kg, or 2 g/kg dose in the CIDP clinical study were:





Skin Irritation: 10%

• 18% were moderate • 3% were severe

• 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

• 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

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Pressure: 8%



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Why PANZYGA?

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.

E

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

SELECTED SAFETY INFORMATION contact your HCP or call emergency services:

- swelling of the lining around your brain
- elsewhere in the body

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 blood pressure and temperature will be checked during treatment



Your infusion time will vary and could take several hours

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

PANZYGA can cause serious side effects. If any of the following problems occur after starting PANZYGA, stop the infusion immediately and

• 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

• 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

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





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



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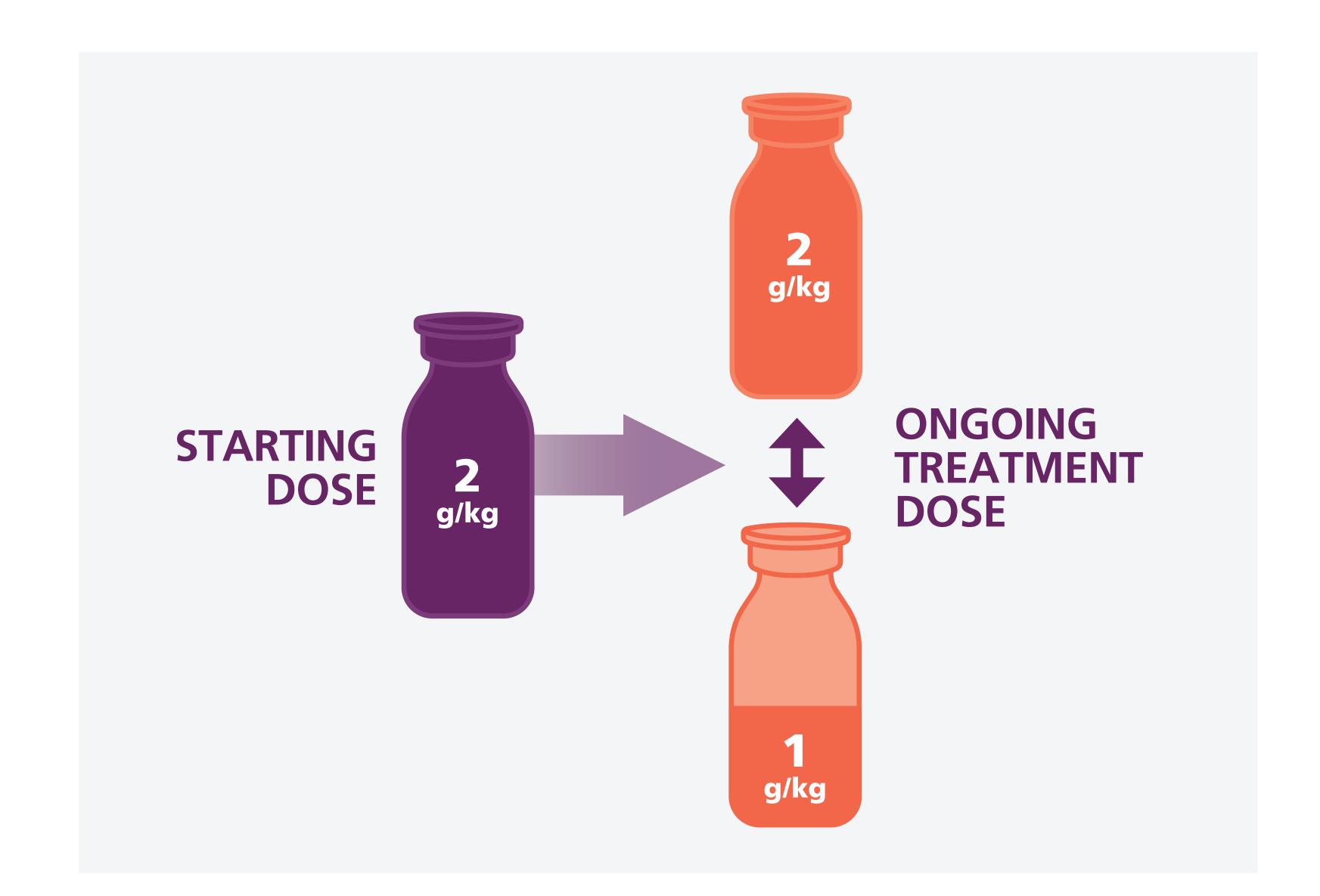
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Why PANZYGA?

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 maintenance dose for your ongoing treatments. This dose can be adjusted as needed.



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

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: (continued) • 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

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All doses are split over the course of 2 days



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Why PANZYGA?

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=U.S. Food and Drug Administration.

SELECTED SAFETY INFORMATION contact your HCP or call emergency services: (continued)

- 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





- PANZYGA can cause serious side effects. If any of the following problems occur after starting PANZYGA, stop the infusion immediately and
- Ask your HCP whether you should have rescue medications available, such as antihistamines or epinephrine.
- Please click <u>here</u> for Full Prescribing Information, including complete BOXED WARNING.

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PANZYGA support

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 <u>Panzygalnfo.com</u>

| | With the Pfizer PANZYGA Co-Pay Program | panzyga |
|---|--|---|
| 126 | Eligible patients may pay as little as | Immune Globulin |
| - Certa | \$0 for PANZYGA* | Intravenous (Human) - ifa 10% Liquid Preparation |
| | | {pronounced: pan-zee-quh |
| | Patients must have commercial insurance to be eligible Patients are not eligible if they are enrolled in a state or federally funded insurance progra | im |
| Not actual patients. | *Eligible, commercially insured patients may pay as little as \$0 for PANZYGA and may receive a maximum ben \$12,500 per year or the cost of patient's co-pay in a 12-month period (whichever is less) for claims received b Terms and conditioned/eliability recursivements abork. See full terms and conditions on page 30 or visit Panzwach | y the program. |
| | See terms and conditions and other details on the following pages. | |
| thrombocytopenia (cl] | obulin Intravenous [Human] – ifas) is indicated for the treatment of primary humoral immunodeficiency (PI) in patie P) in adults and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. | |
| people and contains a | iedicine for infusion that contains immunoglobulin G (IgG), which are proteins that help fight infection. It is made f ntibodies. For patients with PI, PANZYGA helps replace the missing antibodies in the body. For patients with CITP, PI blood clot) to control or prevent bleeding. For patients with CIDP, PANZYGA may help improve mobility and har | ANZYGA helps the body maintain more platelets |
| PANZYGA is given into | a vein (intravenously) in a hospital, infusion center, doctor's office, or at home by a trained healthcare provider (HO | P). |
| SELECTED SAFETY | INFORMATION | |
| See full prescribin | VBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE g information for complete BOXED WARNING | |
| | occur with immune globulin intravenous (IGIV) products, including PANZYGA. Risk factors may include: conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hy n. acute renal failure. osmotic neohropathv. and death may occur with the administration of IGIV produ | perviscosity, and cardiovascular risk factors. |
| | acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. PANZY | GA does not contain sucrose. |
| Renal dysfunctio dysfunction and | | |
| Renal dysfunctio dysfunction and For patients at ris | k of thrombosis, renal dysfunction, or acute renal failure, administer PANZYGA at the minimum infusion r Iministration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at ris | k for hyperviscosity. |

Co-Pay Program Brochure Provides details about the Pfizer PANZYGA Co-Pay Program

Sign up for *mypdnzygd*^{**}

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

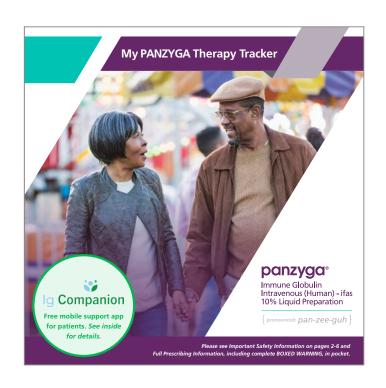
SELECTED SAFETY INFORMATION What are the possible or reasonably likely side effects for PANZYGA?

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

- Headache
- Nausea
- Fever
- Increased blood pressure
- Dermatitis
- Fatigue

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.





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 Helps you prepare for IVIg therapy





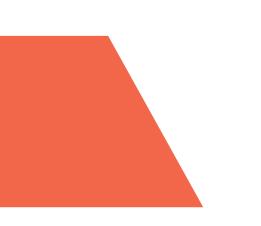
Sign-up at <u>Panzygalnfo.com</u>.

- Abdominal pain
- Dizziness
- Anemia

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Why PANZYGA?

Financial support to help eligible patients



- be eligible

*Eligible, commercially insured patients may pay as little as \$0 for PANZYGA and may receive a maximum benefit of \$12,500 per year or the cost of patient's co-pay in a 12-month period (whichever is less) for claims received by the program. Terms and conditions/eligibility requirements apply. See full terms and conditions at <u>PanzygaCoPay.com</u>.



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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.

With the Pfizer PANZYGA Co-Pay **Program, eligible patients may** pay as little as \$0 for PANZYGA*

Patients must have commercial insurance to

• 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.

- - if you're eligible

- Abdominal pain
- Dizziness
- Anemia

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Pfizer offers Pfizeriguide

Pfizer IGuide[™] can help you:

– Understand your insurance coverage and outof-pocket costs for your prescribed PANZYGA, as well as identify financial assistance options for which you may be eligible

– Enroll in the Pfizer PANZYGA Co-Pay Program,

 Call Pfizer IGuide[™] with questions at 1-844-448-4337 Monday through Friday, 8 AM to 8 PM ET or visit www.PfizerlGuide.com



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Why PANZYGA?

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?

Who is eligible for the Pfizer Pledge Warranty Program?



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 **PanzygaInfo.com**

Not available for residents of Puerto Rico. ⁺Terms and conditions/eligibility requirements apply. See full terms and conditions at <u>PanzygaWarranty.com</u>. ^{}Single treatments may be given over 1 or more days.

SELECTED SAFETY INFORMATION Do not use PANZYGA if you:

PfizerPledge^m

WARRANTY PROGRAM FOR PANZYGA® (Immune Globulin Intravenous [Human] - ifas)

• 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

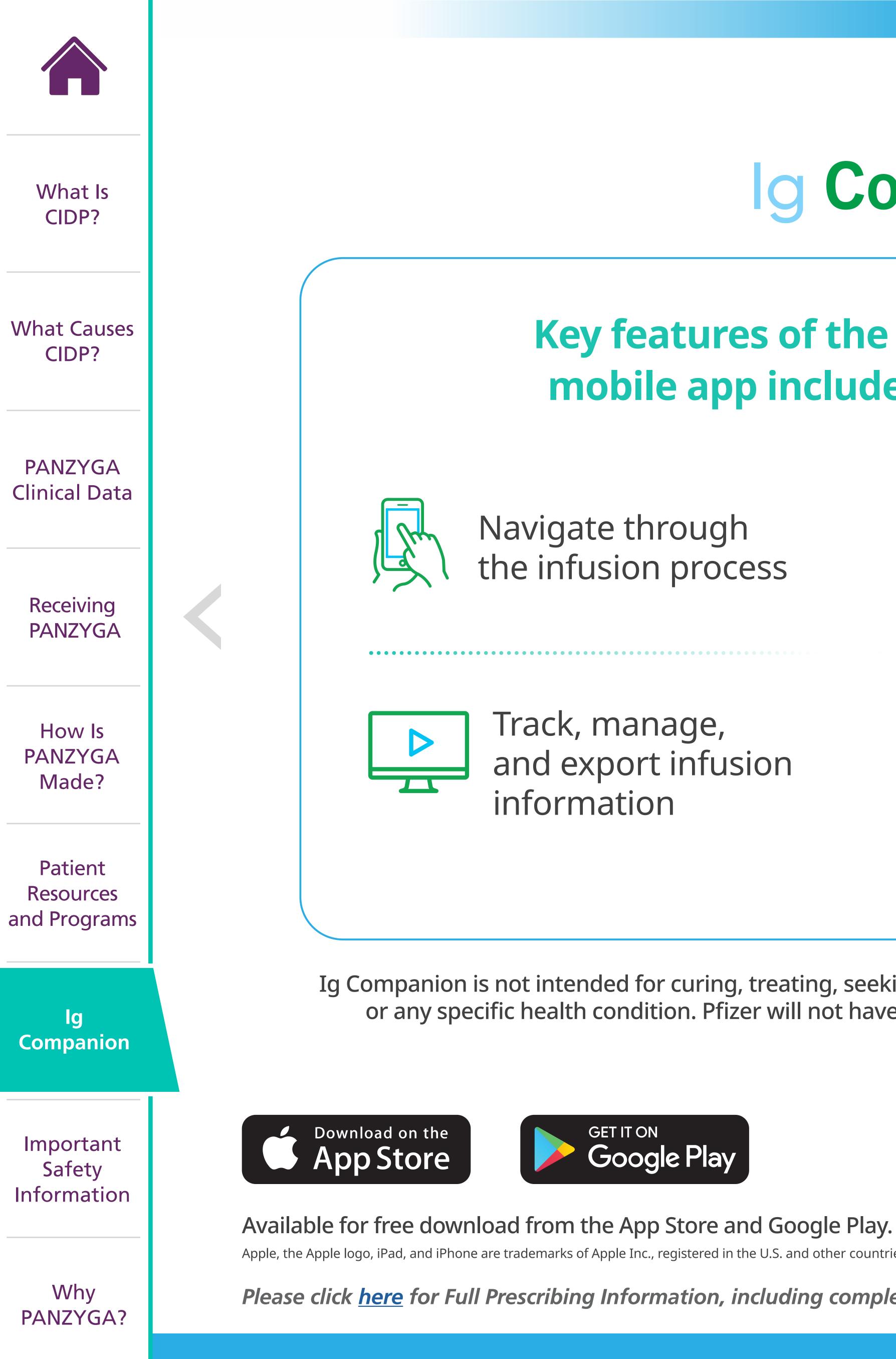
• The Pfizer Pledge Warranty Program is available to adult, cash-paying or commercially insured patients (those with employer-sponsored or private insurance) prescribed PANZYGA for CIDP whose healthcare provider discontinues treatment for clinical reasons before the fifth treatment^{*} • Patients are 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

• 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

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

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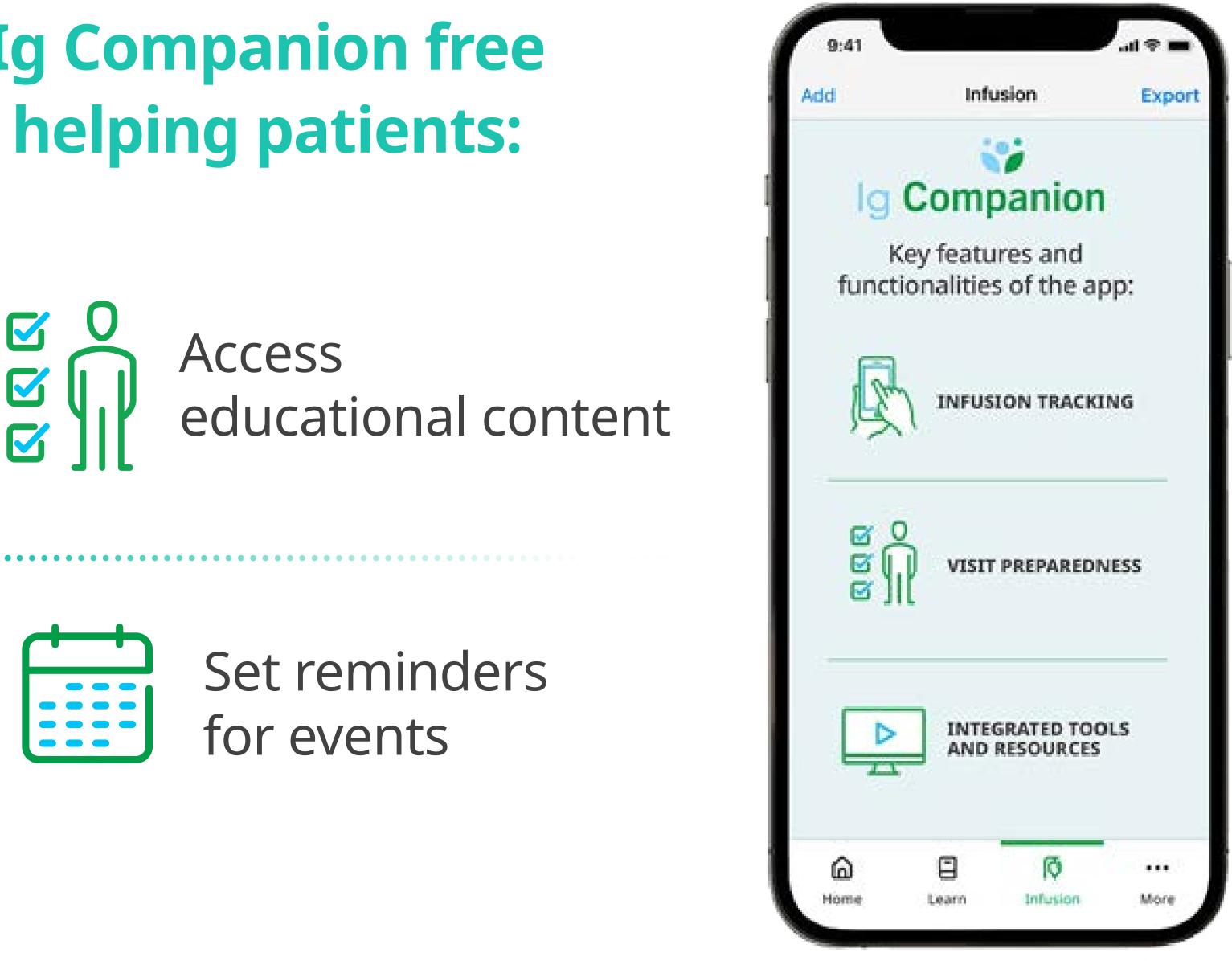






Key features of the Ig Companion free mobile app include helping patients:

Navigate through the infusion process



Track, manage, and export infusion



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.



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Indications and Usage and Important **Safety Information**

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 maintain 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).

IMPORTANT SAFETY INFORMATION

See full prescribing information for complete BOXED WARNING

- containing sucrose. PANZYGA does not contain sucrose.
- assess blood viscosity in patients at risk for hyperviscosity.

Do not use PANZYGA if you:

Please click here for Full Prescribing Information, including complete BOXED WARNING.

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

• 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

• 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

• 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 should I know before taking PANZYGA?

- tell your healthcare provider that you take PANZYGA
- Decreased kidney function and kidney function failure can occur

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:

- irritation and swelling of the lining around your brain
- lungs, or elsewhere in the body

- Fever over 100°F. This could be a sign of an infection
- 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
- Nausea
- Dermatitis
- Fever
- Fatigue

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

• PANZYGA can make vaccines (like measles/mumps/rubella or chickenpox vaccines) work less effectively for you. Before you get any vaccines,

• 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

• 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

• 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,

• 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

• Headache, fatigue or confusion, vision problem, chest pain, difficulty breathing, irregular heartbeat, or pounding in your chest, neck, or ears. These

- Abdominal pain
- Dizziness
- Anemia





What Causes CIDP?

PANZYGA **Clinical Data**

Receiving PANZYGA

How Is PANZYGA Made?

Patient Resources and Programs

lg Companion

Important Safety Information

Why **PANZYGA?**

Why PANZYGA?



PANZYGA is the first and only **IVIg therapy** with 2 FDA-approved ongoing treatment doses

*Response to treatment was an improvement in a patient's score based on an examination that measures arm and leg mobility . 80% of patients (55 of 69) who took 1 g/kg showed improvement and 92% of patients (33 of 36) who took 2 g/kg showed improvement. Dose-dependent increases in headache were observed in 2 g/kg treatment group. ⁺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. *Patient self-reporting of pain was based on an 11-point scale, ranging from 0 (no pain) to 10 (worst possible pain). Patients who received the 1 g/kg dose reported 47% less pain and patients receiving the 2 g/kg dose reported 43% less pain.



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 <u>www.fda.gov/MedWatch</u> or call 1-800-FDA-1088.

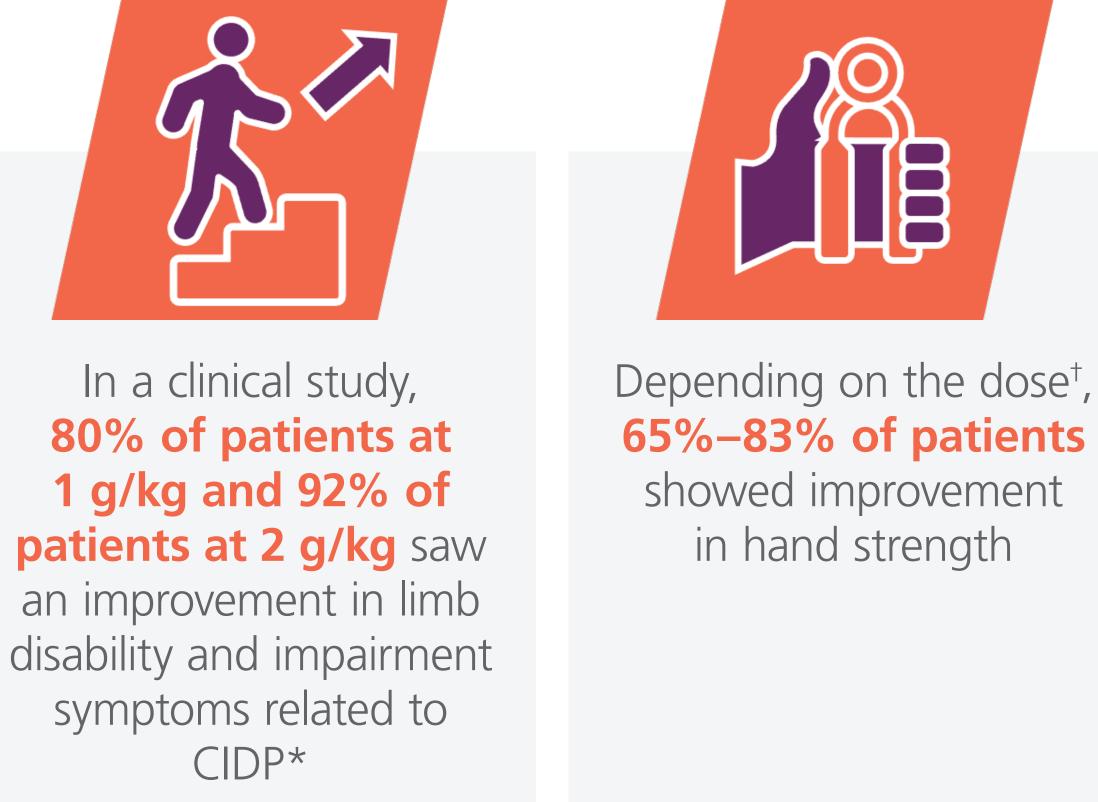
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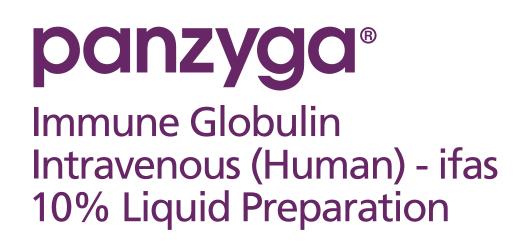
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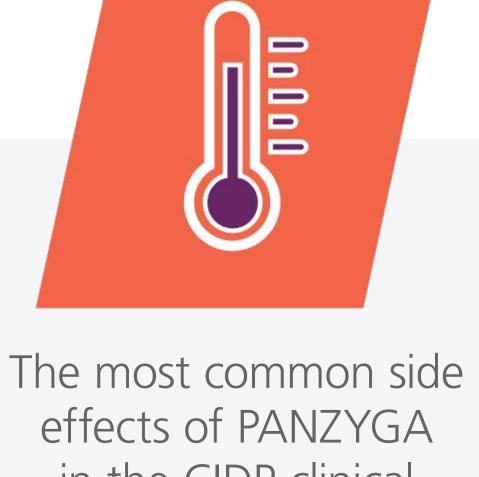
Visit **PanzygaInfo.com** for more information

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Patients reported on average approximately 45% less pain[‡]



in the CIDP clinical study were headache, fever, skin irritation, and increased blood pressure. Allergic reactions may occur

