the modified intention-to-treat (MITT) population. The MITT population consisted of subjects who completed the wash-in/wash-out period and received at least one infusion of HIZENTRA during the efficacy period.

Although 5% of the administered doses could not be verified, the weekly median doses of HIZENTRA ranged from 72 to 379 mg/kg body weight during the efficacy period. The mean dose was 213.2 mg/kg, which was 149% of the previous IGIV dose.

In the study, the number of infusion sites per infusion ranged from 1 to 12. In 73% of infusions, the number of infusion sites was 4 or fewer. Up to 4 simultaneous infusion sites were permitted using 2 pumps; however, more than 4 sites could be used consecutively during one infusion. The infusion flow rate did not exceed 50 mL per hour for all infusion sites combined. During the efficacy period, the median duration of a weekly infusion ranged from 1.6 to 2.0 hours.

The study evaluated the annual rate of serious bacterial infections (SBIs), defined as bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess. The study also evaluated the annual rate of any infections, the use of antibiotics for infection (prophylaxis or treatment), the days out of work/school/kindergarten/day care or unable to perform normal activities due to infections, hospitalizations due to infections, and serum IgG trough levels.

Table 10 summarizes the efficacy results for subjects in the efficacy period (MITT population) of the study. No subjects experienced an SBI in this study.

Table 10. Summary of Efficacy Results (MITT Population)

Number of subjects (efficacy period)	38
Total number of subject days	12,697
Infections	
Annual rate of SBIs*	0 SBIs per subject year†
Annual rate of any infections	2.76 infections/subject year‡
Antibiotic use for infection (prophylaxis or treatment)	
Number of subjects (%)	27 (71.1)
Annual rate	48.5 days/subject year
Total number of subject days	12,605
Days out of work/school/kindergarten/day care or unable to perform normal activities due to infections	
Number of days (%)	71 (0.56)
Annual rate	2.06 days/subject year
Hospitalizations due to infections	
Number of days (%)	7 (0.06)§
Annual rate	0.2 days/subject year

* Defined as bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess.
† Upper 99% confidence limit: 0.132.
‡ 95% confidence limits: 2.235; 3.370.
§ Based on 1 subject.

The mean IgG trough levels increased by 24.2%, from 1009 mg/dL prior to the study to 1253 mg/dL during the efficacy period.

European Study

In a prospective, open-label, multicenter, single-arm, clinical study conducted in Europe, 51 adult and pediatric subjects with PI switched from monthly IGIV (31 subjects) or weekly IGSC (20 subjects) to weekly treatment with HIZENTRA. For the 46 subjects in the efficacy analysis, the weekly mean dose in the efficacy period was 120.1 mg/kg (range 59 to 243 mg/kg), which was 104% of the previous weekly equivalent IGIV or weekly IGSC dose. None of the subjects had an SBI during the efficacy period, resulting in an annualized rate of 0 (upper one-sided 99% confidence limit of 0.192) SBIs per subject. The annualized rate of any infections was 5.18 infections per subject for the efficacy period.

14.2 Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

A multicenter, double-blind, randomized, placebo-controlled, parallel-group phase 3 study evaluated the efficacy, safety, and tolerability of 2 different weekly doses of HIZENTRA (0.4 g/kg body weight and 0.2 g/kg body weight) versus placebo in 172 adult subjects with CIDP and previously treated with IGIV (PATH study). The mean treatment duration was 129 days in the 0.4 g/kg HIZENTRA group and 118.9 days in the 0.2 g/kg HIZENTRA group (treatment duration up to 166 and 167 days in each group, respectively). Subjects generally used 4 infusion sites in parallel (maximum: 8 sites in parallel). Subjects infused an average of 20 mL per infusion site (maximum: 50 mL/site) with an infusion rate of 20 mL/h (maximum: 50 mL/h) and volumes up to 140 mL per infusion session. The infusion time was approximately 1 hour.

The main endpoint was the percentage of subjects who had a CIDP relapse or were withdrawn for any other reason during the SC Treatment Period. CIDP relapse was defined as a ≥1 point increase in adjusted Inflammatory Neuropathy Cause and Treatment [INCAT] score compared with baseline. Both HIZENTRA doses demonstrated superiority over placebo for the main endpoint (32.8% for 0.4 g/kg HIZENTRA and 38.6% for 0.2 g/kg HIZENTRA compared with 63.2% for placebo, $p<0.001$ or $p=0.007$, respectively), with no statistically significant difference between the doses. When only considering relapse, the CIDP relapse rates were 19.0% for 0.4 g/kg HIZENTRA and 33.3% for 0.2 g/kg HIZENTRA compared with 56.1% for placebo ($p<0.001$ or $p=0.012$, respectively), with no statistically significant difference between the doses. Eighty-one percent (81%) and 67% of HIZENTRA-treated subjects remained relapse-free (0.4 g/kg body weight and 0.2 g/kg body weight, respectively); 44% of placebo subjects remained relapse-free for up to 24 weeks.

A Kaplan-Meier Plot of time to CIDP relapse or withdrawal for any other reason is shown in Figure 1.

Figure 1. Kaplan-Meier Plot Time to CIDP Relapse or Withdrawal for Any Other Reason

Subjects in both HIZENTRA dose groups remained relatively stable while subjects in the placebo group deteriorated in mean INCAT score, mean grip strength, mean Medical Research Council sum score, and mean Rasch-built Overall Disability Scale (R-ODS) centile score.

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16 HOW SUPPLIED/STORAGE AND HANDLING

HIZENTRA is supplied in a single-use prefilled syringe or a tamper-evident vial containing 0.2 grams of protein per mL of preservative-free liquid. The HIZENTRA packaging components are not made with natural rubber latex.

Each product presentation includes a package insert and the following components:

Table 11: How Supplied

Prefilled Syringes

Presentation	Carton NDC Number	Components
5 mL	44206-456-21	Prefilled syringe containing 1 gram of protein (NDC 44206-456-94)
10 mL	44206-457-22	Prefilled syringe containing 2 grams of protein (NDC 44206-457-95)
20 mL	44206-458-24	Prefilled syringe containing 4 grams of protein (NDC 44206-458-96) with plunger rod.

Vials:

Presentation	Carton NDC Number	Components
5 mL	44206-451-01	Vial containing 1 gram of protein (NDC 44206-451-90)
10 mL	44206-452-02	Vial containing 2 grams of protein (NDC 44206-452-91)
20 mL	44206-454-04	Vial containing 4 grams of protein (NDC 44206-454-92)
50 mL	44206-455-10	Vial containing 10 grams of protein (NDC 44206-455-93)

Storage and Handling

- Store the HIZENTRA prefilled syringe or vial in its original carton to protect it from light.
- Each prefilled syringe or vial label contains a peel-off strip with the prefilled syringe or vial size and product lot number for use in recording doses in a patient treatment record.
- When stored at room temperature (up to 25°C [77°F]), HIZENTRA is stable for up to 30 months, as indicated by the expiration date printed on the outer carton of the prefilled syringe or vial label.
- Do not shake the HIZENTRA prefilled syringe or vial.
- Do not freeze. Do not use product that has been frozen.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Information for Patients and Instructions for Use).

Inform patients to immediately report the following signs and symptoms to their healthcare provider:

- Hypersensitivity reactions to HIZENTRA (including hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis) *[see Warnings and Precautions (5.1)]*.
- Pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body *[see Warnings and Precautions (5.2)]*.
- Severe headache, neck stiffness, drowsiness, fever, sensitivity to light, painful eye movements, nausea, and vomiting *[see Warnings and Precautions (5.3)]*.
- Decreased urine output, sudden weight gain, fluid retention/edema, and/or shortness of breath *[see Warnings and Precautions (5.4)]*.
- Fatigue, increased heart rate, yellowing of the skin or eyes, and dark-colored urine *[see Warnings and Precautions (5.5)]*.
- Severe breathing problems, lightheadedness, drops in blood pressure, and fever *[see Warnings and Precautions (5.6)]*.

Inform patients that because HIZENTRA is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent *[see Warnings and Precautions (5.7) and Description (11)]*.

Inform patients that HIZENTRA may interfere with the response to live virus vaccines (e.g., measles, mumps, rubella, and varicella) and to notify their immunizing physician of recent therapy with HIZENTRA *[see Drug Interactions (7)]*.

Home Treatment with Subcutaneous Administration

- If self-administration is deemed to be appropriate, ensure that the patient receives clear instructions and training on subcutaneous administration in the home or other appropriate setting and has demonstrated the ability to independently administer subcutaneous infusions.
- Ensure the patient understands the importance of adhering to their prescribed administration schedule to maintain appropriate steady IgG levels.
- Instruct patients to scan the prefilled syringe or vial if recording the infusion electronically and keep a diary/log book that includes information about each infusion such as, the time, date, dose, lot number(s) and any reactions.
- Inform the patient that mild to moderate local infusion-site reactions (e.g., swelling and redness) are a common side effect of subcutaneous therapy, but to contact their healthcare professional if a local reaction increases in severity or persists for more than a few days.
- Inform patients of the importance of having an infusion needle long enough to reach the subcutaneous tissue and of changing the actual site of infusion with each infusion. Explain that HIZENTRA is for subcutaneous infusion only.
- Inform patients to consider adjusting the infusion-site location, volume per site, and rate of infusion based on how infusions are tolerated.
- Inform patient to interrupt or terminate the HIZENTRA infusion if a hypersensitivity reaction occurs.
- Inform PI patients that they should be tested regularly to make sure they have the correct levels of HIZENTRA (IgG) in their blood. These tests may result in adjustments to the HIZENTRA dose.

Information for Patients
HIZENTRA®
(hi-ZEN-tra)
Immune Globulin Subcutaneous (Human), 20% Liquid

Information for Patients

This patient package insert summarizes important information about HIZENTRA. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare professional, and it does not include all of the important information about HIZENTRA. If you have any questions after reading this, ask your healthcare professional.

What is the most important information I should know about HIZENTRA?

HIZENTRA is supposed to be infused under your skin only. DO NOT inject HIZENTRA into a blood vessel (vein or artery).

What is HIZENTRA?

HIZENTRA is a prescription medicine used to treat primary immune deficiency (PI) and chronic inflammatory demyelinating polyneuropathy (CIDP). HIZENTRA is made from human blood. HIZENTRA contains antibodies called immunoglobulin G (IgG). People with PI get a lot of infections, and IgG fights germs (bacteria and viruses). People with CIDP have a form of autoimmune disease where it is believed the body's defenses attack the nerves and cause muscle weakness and numbness mainly in the legs and arms. IgG is believed to help protect the nerve from being attacked.

Who should NOT take HIZENTRA?

Do not take HIZENTRA if you have too much proline in your blood (called "hyperprolinemia") or if you have had reactions to polysorbate 80.

Tell your doctor if you have had a serious reaction to other immune globulin medicines or if you have been told that you also have a deficiency of the immunoglobulin called IgA.

Tell your doctor if you have a history of heart or blood vessel disease or blood clots, have thick blood, or have been immobile for some time. These things may increase your risk of having a blood clot after using HIZENTRA. Also tell your doctor what drugs you are using, as some drugs, such as those that contain the hormone estrogen (for example, birth control pills), may increase your risk of developing a blood clot.

How should I take HIZENTRA?

You will take HIZENTRA through an infusion, only under your skin. You will place up to 8 needles into different areas of your body each time you use HIZENTRA. The needles are attached to a pump with an infusion tube. For PI, you can have infusions as often as every day up to every two (2) weeks. For CIDP, infusions are given once weekly (in 1 or 2 sessions conducted on 1 day or 2 consecutive days). For weekly infusions, it can take about 1 to 2 hours to complete an infusion; however, this time may be shorter or longer depending on the dose and frequency your doctor has prescribed for you.

Instructions for using HIZENTRA are at the end of this patient package insert (see "How do I use HIZENTRA?"). Do not use HIZENTRA by yourself until you have been taught how by your doctor or healthcare professional.

What should I avoid while taking HIZENTRA?

Vaccines may not work well for you while you are taking HIZENTRA. Tell your doctor or healthcare professional that you are taking HIZENTRA before you get a vaccine.

Tell your doctor or healthcare professional if you are pregnant or plan to become pregnant, or if you are nursing.

What are possible side effects of HIZENTRA?

The most common side effects with HIZENTRA are:

- Redness, swelling, itching, and/or bruising at the infusion site
- Headache/migraine
- Nausea and/or vomiting
- Pain (including pain in the chest, back, joints, arms, legs)
- Fatigue
- Diarrhea
- Stomach ache/bloating
- Cough, cold or flu symptoms
- Rash (including hives)
- Itching
- Fever and/or chills
- Shortness of breath
- Dizziness
- Fall
- Runny or stuffy nose

Tell your doctor right away or go to the emergency room if you have hives, trouble breathing, wheezing, dizziness, or fainting. These could be signs of a bad allergic reaction.

Tell your doctor right away if you have any of the following symptoms. They could be signs of a serious problem.

- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens

on deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body. These could be signs of a blood clot.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of a brain swelling called meningitis.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a blood problem.
- Chest pains or trouble breathing.
- Fever over 100ºF. This could be a sign of an infection.

Tell your doctor about any side effects that concern you. You can ask your doctor to give you more information that is available to healthcare professionals.

How do I use HIZENTRA?

Infuse HIZENTRA only after you have been trained by your doctor or healthcare professional. Below are step-by-step instructions to help you remember how to use HIZENTRA. Ask your doctor or healthcare professional about any instructions you do not understand.

Instructions for use

For subcutaneous use only

HIZENTRA is provided in a carton containing:
- Single-use prefilled syringes (5 mL, 10 mL, and 20 mL) or
- Single-use vials (5, 10, 20, and 50 mL).

Store HIZENTRA in its original carton at room temperature until ready to use. Do not use the prefilled syringe or vial if the packaging is damaged.

Step 1: Assemble supplies

Gather the HIZENTRA prefilled syringe(s) or vial(s), all supplies, and infusion log book:

Infusion administration tubing
Subcutaneous needle or catheter sets
Syringes
Transfer device or needle(s)
Gauze and tape, or transparent dressing
Infusion pump
Sharps container
Alcohol wipes
Antiseptic skin preps

Step 2: Clean surface

Clean a table or other flat surface.

Step 3: Wash hands

Thoroughly wash and dry your hands (Figure 1).

Figure 1

Step 4: Check prefilled syringe(s) or vial(s)

- If using prefilled syringes, carefully peel back the transparent covering from the tray and inspect the protective cap. **Peel back the outer layer of the wrap-around label** to allow for viewing of HIZENTRA through the fully transparent inner layer, but don't remove the label completely (Figure 2).

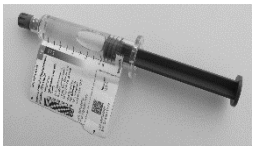

Figure 2

- If using vials, inspect the protective cap of the vials (Figure 3).

Carefully inspect each prefilled syringe(s) or vial(s) of HIZENTRA. **Do not use the prefilled syringe or vial if**:
- o The liquid looks cloudy, contains particles, or has changed color.
- o The protective cap of the prefilled syringe or the vial is missing or defective.
- o The expiration date on the label has passed.

Figure 3

Step 5: Preparation of HIZENTRA for infusion
- If using HIZENTRA prefilled syringes, go to Step 5.1
- If using HIZENTRA vials, go to Step 5.2

Step 5.1: HIZENTRA prefilled syringe(s)
- The 5 mL, 10 mL, and 20 mL prefilled syringes are supplied and ready to use. The 5 mL and 10 mL prefilled syringes are fully assembled (Figure 4). For the 20 mL prefilled syringe, screw the plunger rod onto the prefilled syringe stopper prior to use (Figure 5).
- HIZENTRA prefilled syringes can be placed directly in the infusion pump if the syringe size matches the pump requirements. If the prefilled syringe can be placed directly in the infusion pump, then go to Step 6.

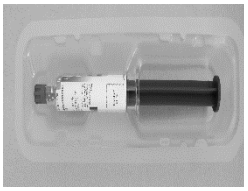

Figure 4

NOTE:
An additional adapter may be required for the HIZENTRA prefilled syringes to fit properly in the infusion pump. Check with the provider of your supplies for the appropriate adapter and installation instructions.

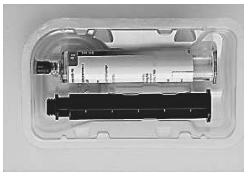

Figure 5

- If the HIZENTRA prefilled syringe size does not match the infusion pump requirements, transfer the contents of the prefilled syringe to another syringe of a size specific for the infusion pump by following the directions below:
  - o Use a syringe-to-syringe transfer device (tip-to-tip connector) (Figure 6).

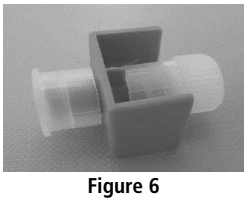

Figure 6

  - o Remove the protective cap from the prefilled syringe. Attach the transfer device by twisting it onto the prefilled syringe. Attach the empty syringe by screwing it onto the other side of the transfer device (Figure 7).

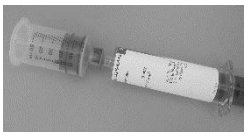

Figure 7

  - o Push the plunger of the prefilled syringe to transfer HIZENTRA from the prefilled syringe to the empty syringe.
    - o Repeat this step if multiple prefilled syringes are necessary to achieve the prescribed dose. Remove the empty prefilled syringe and attach another prefilled syringe to the transfer device.
  - o After the transfer is complete, remove the empty prefilled syringe and the transfer device by unscrewing them from the syringe specific for your pump. Connect the filled syringe to the infusion tubing.

Go to Step 6.

Step 5.2: Transfer HIZENTRA from vial to syringe
- Take the protective cap off the vial (Figure 8).
- Clean the vial stopper with an alcohol wipe (Figure 9). Let the stopper dry.
- If using a transfer device, follow the instructions provided by the device manufacturer.

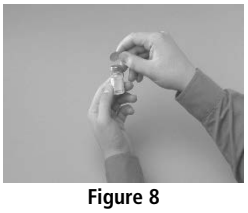

Figure 8

- If using a needle and a syringe to transfer HIZENTRA, follow the instructions below:

Figure 9

- Attach a sterile transfer needle to a sterile syringe (Figure 10).

Figure 10

- Pull out the plunger of the syringe to fill the syringe with air. Make sure the amount of air is the same as the amount of HIZENTRA you will transfer from the vial.
- Put the HIZENTRA vial on a flat surface. Keeping the vial upright, insert the transfer needle into the center of the rubber stopper.
- Check that the tip of the needle is not in the liquid. Then, push the plunger of the syringe down. This will inject the air from the syringe into the airspace of the vial.
- Leaving the needle in the stopper, carefully turn the vial upside down (Figure 11).

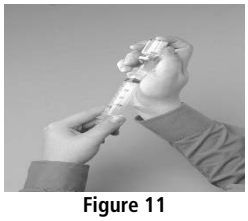

Figure 11

- Slowly pull back on the plunger of the syringe to fill the syringe with HIZENTRA.
- Take the filled syringe and needle out of the stopper. Take off the needle and throw it away in the sharps container.

When using multiple vials to achieve the desired dose, repeat this step.

Step 6: Prepare infusion tubing

- Prepare the infusion pump (following the manufacturer's instructions), including attaching any necessary adapters.
- Prime (fill) the infusion tubing. To prime the tubing, connect the syringe filled with HIZENTRA to the infusion tubing and gently push on the syringe plunger to fill the tubing with HIZENTRA (Figure 12).
- Stop priming before HIZENTRA fluid reaches the needle.
- Insert syringe filled with HIZENTRA into the infusion pump

Figure 12

Step 7: Prepare infusion site(s)

- Select an area on your abdomen, thigh, upper arm, or side of upper leg/hip for the infusion (Figure 13).
- Use a different site with every HIZENTRA infusion. New sites should be at least 1 inch from a previous infusion site.
- Never infuse into areas where the skin is tender, bruised, red, or hard. Avoid infusing into scars or stretch marks.
- You can use up to 8 infusion sites at the same time. If you are using more than one infusion site, at the same time, be sure the infusion sites are at least 2 inches apart. More than one infusion device can be used simultaneously
- Clean the skin at each site with an antiseptic skin prep (Figure 14). Let the skin dry.

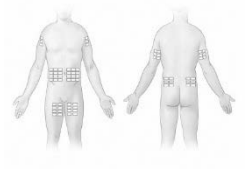

Figure 13

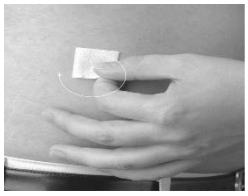

Figure 14

Step 8: Insert needle(s)

- Using two fingers, pinch together the skin around the infusion site. With a quick dart-like motion, insert the needle straight into the skin (Figure 15).

Figure 15

- Put sterile gauze and tape or a transparent dressing over the infusion site (Figure 16). This will keep the needle from coming out.

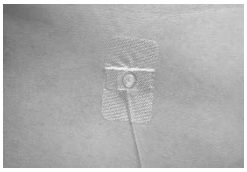

Figure 16

Step 9: Start infusion

- Follow the manufacturer's instructions to turn on the infusion pump (Figure 17).

Figure 17

Step 10: Complete infusion and record treatment (Figure 18)

- When all the HIZENTRA has been infused turn off the infusion pump (if used).
- Remove and dispose of the needle set and cover the infusion site with a protective dressing.
- Peel off the removable part of the label for each prefilled syringe or vial. Put this label in your log book with the date and time of the infusion and include the exact amount of HIZENTRA that you infused. Scan the prefilled syringe or vial if recording the infusion electronically.

Figure 18

Step 11: Clean up

- If applicable, remove adapter from the infusion pump following the manufacturer's instructions.
- Throw away the empty HIZENTRA prefilled syringe(s) or vial(s), along with the used disposable supplies, in the sharps container (Figure 19) in accordance with local requirements.
- Clean and store the infusion pump, following the manufacturer's instructions.

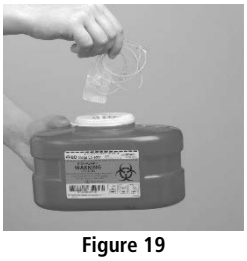

Figure 19

Be sure to tell your doctor about any problems you have doing your infusions. Your doctor may ask to see your treatment diary or log book, so be sure to take it with you each time you visit the doctor's office.

Call your doctor for medical advice about side effects. You can also report side effects to FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

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