elaprase® (idursulfase)

UNDERSTANDING ELAPRASE

What is ELAPRASE® (Idursulfase)?

ELAPRASE is a prescription medicine for patients with Hunter syndrome.

ELAPRASE has been shown to improve walking ability in patients 5 yrs and older.

In patients 16 months to 5 yrs old, ELAPRASE did not show improvement in disease-related symptoms or long term clinical result; however, treatment with ELAPRASE has reduced spleen size similarly to patients 5 yrs and older.

It is not known if ELAPRASE is safe and effective in children under 16 months old.

IMPORTANT SAFETY INFORMATION

RISK OF SERIOUS ALLERGIC REACTIONS:

Some patients have experienced serious allergic reactions (including life-threatening anaphylactic reactions) during and up to 24 hours after treatment, regardless of how long they were taking ELAPRASE. Anaphylactic reactions are immediate and include breathing problems, low oxygen levels, low blood pressure, hives and/or swelling of the throat or tongue. If a patient (you or your child) has experienced an anaphylactic reaction, the patient may require an extended period of observation by the patient's healthcare team. If you or your child has breathing problems, a fever, or a respiratory illness, you or your child may be at risk of life-threatening worsening of those conditions due to allergic reactions from ELAPRASE. Your healthcare team should be advised of those conditions before treatment with ELAPRASE because the information may affect the timing of ELAPRASE treatment.

For Patients and Caregivers

Please see additional Important Safety Information on pages 16–17 and CLICK HERE to see accompanying Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

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For more information,
please visit www.ELAPRASE.com

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Please see Important Safety Information on **pages 16–17** and **CLICK HERE** to see accompanying Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

INTRODUCTION

Living with Hunter syndrome (also known as **mucopolysaccharidosis II or MPS II)** can be challenging, and processing the transition onto a treatment that you may not have heard of before can be overwhelming. This brochure provides an introduction to ELAPRASE in order to help you understand how it works and what to expect.

For further advice and information, please speak to your doctor and visit **www.ELAPRASE.com**, where you can find a variety of resources designed to help you feel supported and informed throughout your treatment journey.

The information contained in this brochure is not intended to replace the care and advice you should receive from your doctor.

IMPORTANT SAFETY INFORMATION (CONTINUED)

You or your child should be closely watched during and after ELAPRASE treatment and you should confirm with your healthcare team in advance of treatment that it is prepared to manage serious allergic reactions, including anaphylactic reactions. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** Those signs may include breathing problems, low blood pressure, rash, hives, itching, flushing, fever and/or headache.

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elaprase® (idursulfase)

WHAT IS ELAPRASE?

- ELAPRASE is a prescription medicine for patients with Hunter syndrome.
- ELAPRASE has been shown to improve walking ability in patients 5 years and older.
- In patients 16 months to 5 years old, ELAPRASE did not show improvement in disease-related symptoms or long term clinical result; however, treatment with ELAPRASE has reduced spleen size similarly to patients 5 years and older.
- It is not known if ELAPRASE is safe and effective in children under 16 months old.
- ELAPRASE is a type of **enzyme replacement therapy (ERT)** intended for Hunter syndrome patients who are unable to produce enough of the **iduronate-2-sulfatase** enzyme themselves.
- ELAPRASE is an “enzyme replacement therapy” because it is a formulation of the enzyme called iduronate-2-sulfatase that is missing or low in people with Hunter syndrome. ELAPRASE is a purified form of the iduronate-2-sulfatase enzyme produced by **recombinant DNA technology** in a human cell line.
- ELAPRASE may affect individuals differently and each person’s experience with ELAPRASE will be unique.

For help with the terminology highlighted in blue throughout this brochure, please refer to the glossary on page 19.

IMPORTANT SAFETY INFORMATION (CONTINUED)

When serious allergic reactions happened during clinical trials, later ELAPRASE treatments were managed with allergy-controlling drugs before or during treatment, a slower rate of ELAPRASE treatment, and/or early discontinuation of treatment.

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HOW DOES ELAPRASE WORK?

The active substance in ELAPRASE is an enzyme that breaks down glycosaminoglycans (GAGs) that build up inside people with Hunter syndrome, causing the signs and symptoms of the condition. For example, the buildup of GAGs within organs such as the liver and spleen results in enlarged organ size.

As outlined on the next page, ELAPRASE is intended to reduce the levels of GAGs in cells.

HOW IS ELAPRASE ADMINISTERED?

ELAPRASE is administered intravenously (by infusion into a vein) once a week or as prescribed by a qualified healthcare professional, with appropriate emergency medical support readily available.

Infusions typically last up to 3 hours, but patients may require longer infusion times if hypersensitivity reactions occur, and additional time for preparation and observation may be needed.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Children with serious genetic mutations may be at risk for allergic reactions, serious side effects and antibody development. In a clinical study of children 7 years and younger, patients with certain types of genetic mutations experienced a higher number of allergic reactions, serious side effects, and development of an immune response to treatment. This immune response may interfere with the effectiveness of ELAPRASE. Talk to your healthcare team about whether you or your child may be at risk.

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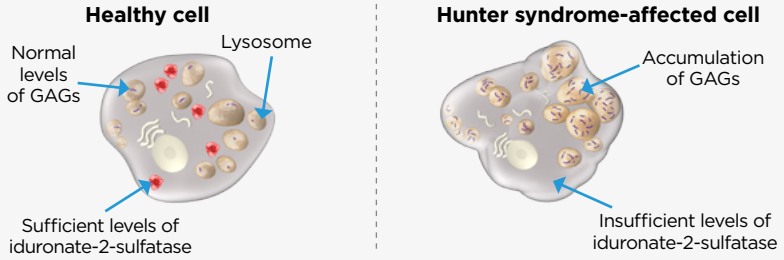
ELAPRASE mechanism of action

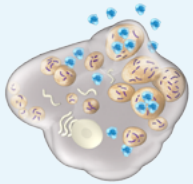
Healthy cell vs. Hunter syndrome-affected cell

In a healthy cell, GAGs are broken down and remain at a healthy level. In the cells of a Hunter syndrome patient, GAGs accumulate in the lysosomes, causing cellular and organ damage. Lysosomes are compartments within a cell.



How ELAPRASE works

After administration, ELAPRASE is absorbed into the cells, where it is intended to act in place of the missing enzyme to break down GAGs.



ELAPRASE-treated cell

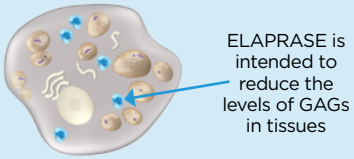


Illustration only. Not intended to imply clinical significance.

For more information about the administration of ELAPRASE, please refer to the ELAPRASE Infusions: What to Expect guide.

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15+ YEARS

ELAPRASE® (idursulfase) is a global brand with over 15 years of real-world experience

ELAPRASE is available in 77 countries* and has been FDA approved since 2006

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1917

First cases of Hunter syndrome characterized, later also known as mucopolysaccharidosis type 2 (MPS II).

1972

Hunter corrective factor found, later known as iduronate-2-sulfatase (I2S), the enzyme deficient or malfunctioning in Hunter syndrome patients.

1990

Discovery of enzyme replacement therapy as a possible treatment for Hunter syndrome.

1990–2000

Development of idursulfase, a purified form of the human I2S enzyme produced by recombinant DNA technology in a continuous human cell line.

2001

Idursulfase enzyme replacement therapy clinical trial program initiated.

2005

Hunter Outcome Survey (HOS) began patient enrollment. HOS is a Takeda-sponsored, global, long-term observational survey of MPS II patients established in order to better understand MPS II.

2006

ELAPRASE receives US Food and Drug Administration (FDA) approval for use in patients with MPS II aged 5 years or older, based on data from the pivotal clinical trial in MPS II patients aged 5–31 years.

10 YEARS 2016

ELAPRASE hits 10-year mark. As of July 2016, 1200 patients from 134 clinics in 33 countries had been enrolled in the Hunter Outcome Survey (HOS), making it the largest global source of data on Hunter syndrome.

ELAPRASE PRESENT DAY

ELAPRASE is the first and only ERT with over 15 years of clinical experience approved for the treatment of Hunter syndrome in the United States. It is additionally approved in 77* countries worldwide.

*Indication and risk information may vary by country.

IMPORTANT SAFETY INFORMATION (CONTINUED)

If you or your child has breathing problems, other respiratory illness, heart problems, or susceptibility to fluid overload, you or your child may be at higher risk of fluid overload during ELAPRASE treatment. Your healthcare team should be advised of those problems before treatment and you should confirm with your healthcare team in advance of treatment that it is appropriately trained to watch for signs of fluid overload and provide the necessary medical support. Patients at risk for fluid overload may require longer observation time.

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Please see additional Important Safety Information on **pages 16–17** and **CLICK HERE** to see accompanying Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

Takeda Patient Support
Your Source for Education and Access

Takeda Patient Support

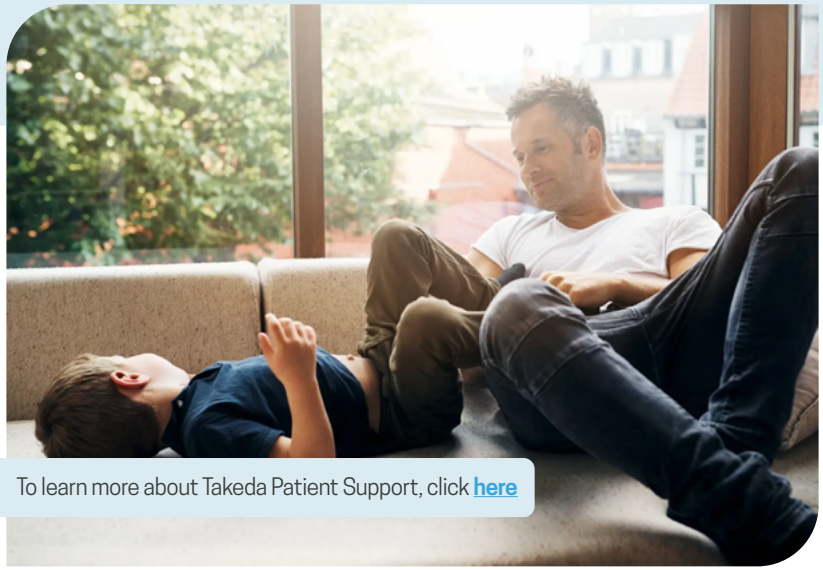
After you and your physician choose a treatment path, Takeda Patient Support is here for you with a range of personalized services for your treatment journey — even when you need to travel away from home.

Our support specialists are here to address your questions and concerns and help get you the answers, resources, and tools you need. Some of the ways we can help include:

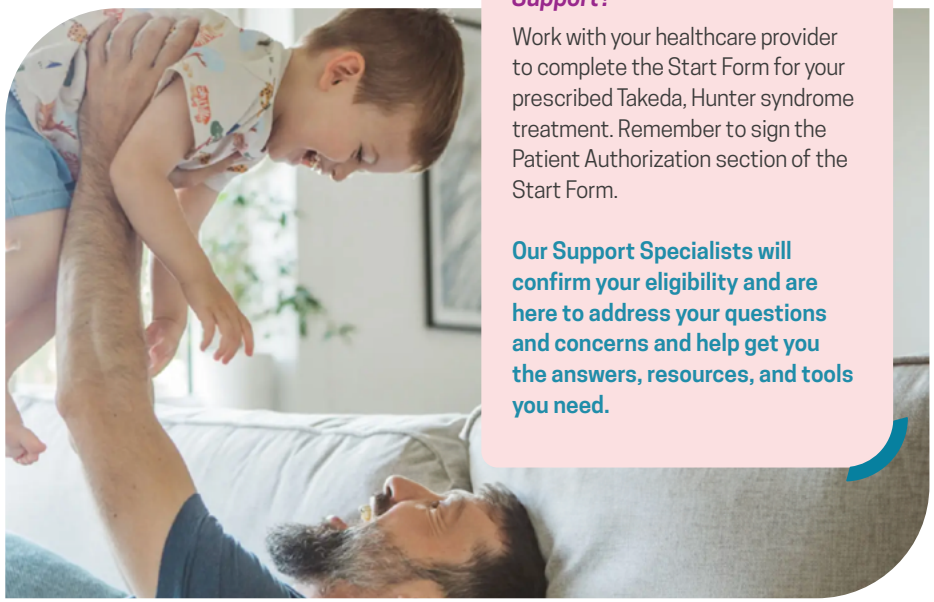
- **Copay** assistance for those who are eligible,* as well as assistance with navigating complex reimbursement and insurance issues
- **Coordination** between your specialty pharmacy and your site of care, even if you are traveling out of town or relocating
- **Helping** you find information, education, and community resources about your condition and Hunter syndrome
- **Assistance** during life transitions like relocation, moving to college, or changing jobs

*To be eligible, you must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Call us for more details.

To download the Takeda Patient Support Start Form, click here



To learn more about Takeda Patient Support, click here



Want to get the person you care for started in Takeda Patient Support?

Work with your healthcare provider to complete the Start Form for your prescribed Takeda, Hunter syndrome treatment. Remember to sign the Patient Authorization section of the Start Form.

Our Support Specialists will confirm your eligibility and are here to address your questions and concerns and help get you the answers, resources, and tools you need.

Our support specialists are never more than a tap or a call away — **1-866-888-0660**, Monday through Friday, 8:30 am to 8:00 pm ET.

If English is not your preferred language, let your support specialist know. The team can communicate over the phone in a variety of languages — including Spanish, and more — using a translation service.

IMPORTANT SAFETY INFORMATION (CONTINUED)

What are possible side effects of ELAPRASE?
The most common side effects of ELAPRASE include:

- In patients aged 5 and older:
  - Headache
  - Itching
  - Muscle and bone pain
  - Hives
  - Diarrhea
  - Cough
- In patients aged 7 years or younger:
  - Fever
  - Rash
  - Vomiting
  - Hives

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FREQUENTLY ASKED QUESTIONS

What is Hunter syndrome?

Hunter syndrome is a genetic disorder that results in a lack of a specific enzyme, iduronate-2-sulfatase. This enzyme is needed to down substances in the body called glycosaminoglycans (GAGs). patients with Hunter syndrome cannot break these substances down, the GAGs gradually build up in most of the organs in the body and can damage them. This causes a range of disease-related signs and symptoms, including diminished lung function and decreased walking ability. Ask your doctor about where to find more information about Hunter syndrome.

What is ELAPRASE?

ELAPRASE is a prescription medicine for patients with Hunter syndrome. ELAPRASE has been shown to improve walking ability in patients 5 years and older. In patients 16 months to 5 years old, ELAPRASE did not show improvement in disease-related symptoms or long term clinical result; however, treatment with ELAPRASE has reduced spleen size similarly to patients 5 years and older. It is not known if ELAPRASE is safe and effective in children under 16 months old.

It is a type of enzyme replacement therapy intended for Hunter syndrome patients who are unable to produce enough of the iduronate-2-sulfatase enzyme themselves.

IMPORTANT SAFETY INFORMATION (CONTINUED)

The most common side effects needing medical attention were allergic reactions, and included rash, hives, itching, flushing, fever, and headache. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** These are not all the possible side effects of ELAPRASE.

Please see additional Important Safety Information on pages 16–17 and CLICK HERE to see accompanying Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

Why does the ELAPRASE prescribing information say that "In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long-term clinical outcome"?

A clinical trial, including patients aged 5 years and older, evaluated walking capacity and lung function, which are considered to be disease-related symptoms, and a 2-year extension study was carried out to gather longer-term data. These symptoms were not evaluated in the trial that included patients aged 16 months to 7 years.

To learn more about ELAPRASE clinical trials, visit www.ELAPRASE.com/what-is-elaprase/clinical-trials

Why does the prescribing information say that "The safety and efficacy of ELAPRASE have not been established in pediatric patients less than 16 months of age"?

The clinical trials that studied ELAPRASE only included patients aged 16 months and older.

Is ELAPRASE a new medication?

No, ELAPRASE has been FDA-approved for use in the U.S. since 2006, and is also approved in 77 other countries after receiving respective marketing authorizations. Indication and risk information may vary by country.

Please see Important Safety Information on pages 16–17 and CLICK HERE to see accompanying Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

FREQUENTLY ASKED QUESTIONS (CONTINUED)

How is treatment with ELAPRASE administered?

ELAPRASE is administered intravenously (by infusion into a vein) once a week by a trained healthcare professional.

For more information on how ELAPRASE is administered and dosed, refer to the **ELAPRASE Infusions: What to Expect** guide, which can be provided by your doctor or downloaded from **www.ELAPRASE.com/resources**

What are the side effects of ELAPRASE?

Allergic reactions, including life-threatening anaphylaxis, have occurred in some patients treated with ELAPRASE. Anaphylactic reactions include breathing problems, low oxygen levels, low blood pressure, hives, and/or swelling of the throat or tongue. Inform your healthcare provider immediately if you notice any of these symptoms beginning.

In clinical trials, the most common side effects, occurring in at least three patients aged 5 years or older, were headache, itching, muscle and bone pain, hives, diarrhea, and cough. Among patients aged 7 years or younger, the most common adverse reactions occurring in at least three patients were fever, rash, vomiting, and hives.

How can I find out if I can switch to home infusions?

Please speak to your doctor about home infusions. Patients who tolerate ELAPRASE infusions well may be able to receive infusions at home under the supervision of a healthcare professional.

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Should the ELAPRASE infusion be postponed if you are unwell?

Inform your healthcare team of any illness prior to the ELAPRASE infusion, and they will decide whether to delay the ELAPRASE infusion. If you or your child has breathing problems, a fever, or a respiratory illness, you or your child may be at risk of life-threatening worsening of those conditions due to allergic reactions to ELAPRASE. Your healthcare team should be advised of those conditions before treatment with ELAPRASE because the information may affect the timing of ELAPRASE treatment.

Please refer to the Important Safety Information on **pages 16–17** and **CLICK HERE** to see the Full Prescribing Information.

What is Takeda Patient Support and how can it help me?

After you and your physician choose a treatment path, Takeda Patient Support is here for you with a range of personalized services for your treatment journey — even when you need to travel away from home. We know that living with Hunter syndrome looks different for everyone.

As we get to know you, understand who you are, and learn what's important to you, we can help provide the support you need when it comes to your treatment.

What is ELAPRASE® (Idursulfase)?

ELAPRASE is a prescription medicine for patients with Hunter syndrome.

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It is not known if ELAPRASE is safe and effective in children under 16 months old.

Important Safety Information

RISK OF SERIOUS ALLERGIC REACTIONS:

Some patients have experienced serious allergic reactions (including life-threatening anaphylactic reactions) during and up to 24 hours after treatment, regardless of how long they were taking ELAPRASE. Anaphylactic reactions are immediate and include breathing problems, low oxygen levels, low blood pressure, hives and/or swelling of the throat or tongue. If a patient (you or your child) has experienced an anaphylactic reaction, the patient may require an extended period of observation by the patient's healthcare team. If you or your child has breathing problems, a fever, or a respiratory illness, you or your child may be at risk of life-threatening worsening of those conditions due to allergic reactions from ELAPRASE. Your healthcare team should be advised of those conditions before treatment with ELAPRASE because the information may affect the timing of ELAPRASE treatment.

You or your child should be closely watched during and after ELAPRASE treatment and you should confirm with your healthcare team in advance of treatment that it is prepared to manage serious allergic reactions, including anaphylactic reactions. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** Those signs may include breathing problems, low blood pressure, rash, hives, itching, flushing, fever and/or headache.

When serious allergic reactions happened during clinical trials, later ELAPRASE treatments were managed with allergy-controlling drugs before or during treatment, a slower rate of ELAPRASE treatment, and/or early discontinuation of treatment.

Please see additional Important Safety Information on page 17 and CLICK HERE to see accompanying Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

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Important Safety Information (continued)

Children with serious genetic mutations may be at risk for allergic reactions, serious side effects and antibody development. In a clinical study of children 7 years and younger, patients with certain types of genetic mutations experienced a higher number of allergic reactions, serious side effects, and development of an immune response to treatment. This immune response may interfere with the effectiveness of ELAPRASE. Talk to your healthcare team about whether you or your child may be at risk.

If you or your child has breathing problems, other respiratory illness, heart problems, or susceptibility to fluid overload, you or your child may be at higher risk of fluid overload during ELAPRASE treatment. Your healthcare team should be advised of those problems before treatment and you should confirm with your healthcare team in advance of treatment that it is appropriately trained to watch for signs of fluid overload and provide the necessary medical support. Patients at risk for fluid overload may require longer observation time.

What are possible side effects of ELAPRASE?

The most common side effects of ELAPRASE include:

- In patients aged 5 and older:
  - Headache
  - Itching
  - Muscle and bone pain
  - Hives
  - Diarrhea
  - Cough
- In patients aged 7 years or younger:
  - Fever
  - Rash
  - Vomiting
  - Hives

The most common side effects needing medical attention were allergic reactions, and included rash, hives, itching, flushing, fever, and headache. **Tell your healthcare team immediately if any signs of an allergic reaction happen.** These are not all the possible side effects of ELAPRASE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For additional safety information, please CLICK HERE for the Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis, and discuss with your doctor.

WHAT OTHER RESOURCES ARE AVAILABLE TO ME?

Websites

ELAPRASE website (www.ELAPRASE.com)
More information about ELAPRASE and its clinical trials, as well as access to many other resources.

MPS Society (www.mpssociety.org)
Hunter syndrome is one of a group of lysosomal storage diseases and this website has resources, support, and ways to connect to other patients.

ELAPRASE guides

ELAPRASE Infusions: What to Expect
Practical advice on preparing for your infusions.

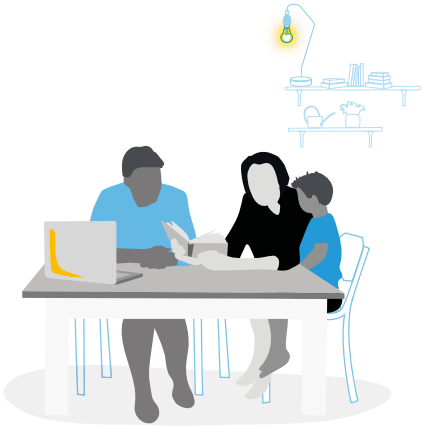
ELAPRASE Reimbursement Guide
Guidance on ELAPRASE coverage and the reimbursement process.

Understanding ELAPRASE: Doctor Discussions
A booklet for you to take to your doctor appointments, designed to help you take notes and ask any questions you might have.

ELAPRASE emails

Stay up to date with ELAPRASE news and updates by signing up to receive occasional emails: www.ELAPRASE.com/stay-updated

These resources are not intended to replace the care and advice you should receive from your doctor.



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GLOSSARY

Enzyme replacement therapy (ERT) – Treatment that works by replacing the missing or deficient enzyme in a disease. ELAPRASE is an ERT and is intended to replace the iduronate-2-sulfatase enzyme in patients with Hunter syndrome.

Glycosaminoglycans (pronounced gli-ko-sah-mee-no-gli-cans) (GAGs) – Long sugar molecules that are a component of connective tissue in the body. GAGs may also be referred to as mucopolysaccharides and build up in patients with Hunter syndrome.

Hypersensitivity – Occurs when a person's body has an undesirable reaction to a substance. In regard to ELAPRASE, allergic reactions can occur upon administration and up to 24 hours after treatment so it is important for your doctor to be prepared to handle this if hypersensitivity does occur in a patient. Please refer to the Important Safety Information on pages 16–17 and **CLICK HERE** to see the Full Prescribing Information.

Iduronate-2-sulfatase (I2S) – This is the name of the enzyme that is missing or deficient in people with Hunter syndrome. ELAPRASE contains a purified form of this enzyme, which is intended to break down the long complex sugar molecules.

Infusion – A therapy that requires administration of a drug through a needle or catheter. ELAPRASE is administered by an infusion so you will go to an infusion center.

Mucopolysaccharidosis (pronounced mew-ko-pol-ee-sak-ah-ride-o-sis) (MPS) II – An alternative name for Hunter syndrome. Hunter syndrome is one type of a collection of diseases called mucopolysaccharidoses, which all involve the accumulation of long sugar molecules that cannot be broken down.

Recombinant DNA technology – Technology that is used to combine different bits of genetic material that can then code for a new protein. ELAPRASE is made up of an enzyme, which is a type of protein, that is created using this method.

Please see additional Important Safety Information on pages 16–17 and CLICK HERE to see accompanying Full Prescribing Information, including Boxed WARNING for Risk of Anaphylaxis.

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1. ELAPRASE Prescribing Information. 2. Whiteman DA, Kimura A. *Drug Des Devel Ther.* 2017; 11: 2467–2480. 3. Hunter C. *Proc R Soc Med.* 1917; 10: 104–116. 4. Martin R *et al. Pediatrics 2008*; 121(2): e377–386. 5. Cantz M *et al. J Biol Chem.* 1972; 247: 5456–5462. 6. Wilson PJ *et al. Proc Natl Acad Sci U S A*. 1990; 87: 8531–8535. 7. Sohn YB *et al. Orphanet J Rare Dis*. 2013; 8: 42. 8. Muenzer J *et al. Genet Med.* 2011; 13: 102–109. 9. Burton BK *et al. J Inherit Metab Dis.* 2017; 40: 867–874. 10. Muenzer J. *Rheumatology (Oxford)*. 2011; 50 Suppl 5: v4–v12. 11. NORD. Mucopolysaccharidosis Type II. Available at: https://rarediseases.org/rare-diseases/mucopolysaccharidosis-type-ii-2/. Accessed February 2022. 12. NINDS NIH. Mucopolysaccharidoses Fact Sheet. Available at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Mucopolysaccharidoses-Fact-Sheet. Accessed February 2022. 13. Healthline. What Is Infusion Therapy and When Is It Needed? Available at: https://www.healthline.com/health/infusion-therapy#conditions-used-for. Accessed February 2022. 14. National Human Genome Research Institute. Recombinant DNA (rDNA). Available at: https://www.genome.gov/genetics-glossary/Recombinant-DNA. Accessed February 2022.

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