ELOCTATE®
[Antihemophilic Factor (Recombinant), Fc Fusion Protein]

# SOME SEE A DRUMMER.

# WE SEE THE NEARLY 70 JOINTS BEHIND EVERY BEAT.

## ELOCTATE PROPHYLAXIS OFFERS BLEED PROTECTION* YOU CAN COUNT ON.

**INDICATION**

**ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] is an injectable medicine that is used to help control and prevent bleeding in people with Hemophilia A (congenital Factor VIII deficiency). Your healthcare provider may give you ELOCTATE when you have surgery.**

***ELOCTATE has been proven to help patients prevent bleeding episodes using a prophylaxis regimen.**

**SELECTED IMPORTANT SAFETY INFORMATION**

**Do not use ELOCTATE if you have had an allergic reaction to it in the past.**

**Please see additional Important Safety Information and full Prescribing Information.**

UP TO 80% OF BLEEDS OCCUR IN THE JOINTS.

# THAT'S WHY YOU NEED A FACTOR VIII TREATMENT YOU CAN COUNT ON.

## IN ADULTS AND ADOLESCENTS ON A PROPHYLACTIC REGIMEN:

**1.6**

1.6 median overall bleeds per year†

**0**

0 median joint bleeds per year†

**~100%**

~100% of target joints resolved‡

**#1**

#1 prescribed Factor VIII for prophylaxis in US[1]

Talk to your doctor to see if ELOCTATE is right for you.

†In the A-LONG study, 164 previously treated adult and adolescent males with sever Hemophilia A received ELOCTATE either every 3 to 5 days, once weekly, or on demand. The ASPIRE extension study included 211 people who completed A-LONG.

‡Data from patients treating prophylactically with ELOCTATE for at least 12 months, who had target joints at enrollment in ASPIRE.

234 out of 235 target joints were resolved. A target joint is defined as a major joint with 3 or more bleeding episodes in a consecutive 6-month period. Target joint resolution is defined as 2 or fewer spontaneous bleeds in a 12-month period.

**SELECTED IMPORTANT SAFETY INFORMATION**

Tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines, have any allergies, are breastfeeding, are pregnant or planning to become pregnant, or have been told you have inhibitors (antibodies) to Factor VIII.

Please see additional Important Safety Information and full Prescribing Information.

[1]#1 prescribed based on HTC reported data as of [June 2020].

## A TREATMENT YOU CAN COUNT ON

# YOU USE YOUR JOINTS MORE THAN YOU THINK.

**It's time to start thinking about how to protect* your joints from bleeds.**

# YOUR JOURNEY STARTS HERE

**Explore the complete guide to a treatment you can count on.**

**You're the kind of guy who uses his joints every day. From the stuff you have to do, to the things you love to do, you're using your joints more than you think. This guide is packed with tons of information and support to help you navigate treatment. Because when it comes to protecting your joints from bleeds, you need a Factor VIII you can count on.**

***ELOCTATE has been proven to help patients prevent bleeding episodes using a prophylaxis regimen.**

GET BLEED PROTECTION.
GET BACK TO
DOING YOUR THING.


Jonathan, on ELOCTATE

Bleed Protection

**For adults and adolescents 12 years and older, ELOCTATE offers bleed and joint bleed protection you can count on. In clinical studies of patients using an individualized prophylaxis regimen†:**

**1.6** median overall bleeds per year.

**0** median joint bleeds per year.

*ELOCTATE has been proven to help patients prevent bleeding episodes using a prophylaxis regimen.

†In the A-LONG study, 164 previously treated adult and adolescent males with severe Hemophilia A received ELOCTATE either every 3 to 5 days, once weekly, or on demand.

**SELECTED IMPORTANT SAFETY INFORMATION**

**Allergic reactions may occur with ELOCTATE. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.**

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# TARGET JOINT RESOLUTION

Target Joint Resolution

**ELOCTATE is a Factor VIII treatment patients can count on when treating prophylactically. Adults and adolescents 12 years and older experienced:**

## ~100% OF TARGET JOINTS RESOLVED†

†Data from patients treating prophylactically with ELOCTATE for at least 12 months, who had target joints at enrollment in ASPIRE. 234 out of 235 target joints were resolved. A target joint is defined as a major joint with 3 or more bleeding episodes in a consecutive 6-month period. Target joint resolution is defined as 2 or less spontaneous bleeds in a 12-month period.

**The ASPIRE extension study includes 150 people who completed A-LONG.**

**SELECTED IMPORTANT SAFETY INFORMATION**

**Your body can also make antibodies called "inhibitors" against ELOCTATE, which may stop ELOCTATE from working properly.**

**Please see additional Important Safety Information and full Prescribing Information.**


When bleeds happen, you need a factor you can count on to resolve them. In clinical studies, adults and adolescents who had a bleed experienced the following results:

IN **8/10** (78%) BLEEDING EPISODES, PATIENTS SAW PAIN RELIEF AND/OR IMPROVEMENT IN SIGNS **OF BLEEDING WITH 1 INFUSION.**

(n=582 bleeds)

**87%** of bleeds were controlled **WITH 1 INFUSION.**

(n=661 bleeds)

**SELECTED IMPORTANT SAFETY INFORMATION**

Additional common side effects of ELOCTATE are headache, rash, joint pain, muscle pain and general discomfort.

Please see additional Important Safety Information and full Prescribing Information.

# BLEED PROTECTION FOR GROWING JOINTS

ELOCTATE®
[Antihemophilic Factor (Recombinant), Fc Fusion Protein]

# CHILDREN'S BLEED PROTECTION AND TARGET JOINT RESOLUTION

Children's Bleed Protection and Target Joint Resolution

**Kids can be kids while they stay protected from bleeds. With ELOCTATE prophylaxis, children under 12 years old saw results they can count on.**

**2.0**
median annual overall bleeds per year*

**0**
median annual joint bleeds per year*

**100% OF TARGET JOINTS RESOLVED†**

*In the Kids A-LONG study, 69 children ages 1-11 received ELOCTATE twice weekly. The ASPIRE extension study included 61 children who completed Kids A-LONG.

†Data from patients treating prophylactically with ELOCTATE for at least 12 months, who had target joints at enrollment in ASPIRE. 9 out of 9 target joints were resolved. A target joint is defined as a major joint with 3 or more bleeding episodes in a consecutive 6-month period. Target joint resolution is defined as 2 or less spontaneous bleeds in a 12-month period.

**SELECTED IMPORTANT SAFETY INFORMATION**

If you have risk factors for developing abnormal blood clots in your body, such as an indwelling venous catheter, treatment with Factor VIII may increase this risk.

Please see additional Important Safety Information and full Prescribing Information.


# BLEED CONTROL FOR THE LITTLE ONES

When bleeds occur in children under 12 years old, you can count on Factor VIII to resolve them.

**IN 9/10 (93%) BLEEDING EPISODES, PATIENTS SAW PAIN RELIEF AND/OR IMPROVEMENT IN SIGNS OF BLEEDING WITH 1 INFUSION.**

(n=75 bleeds)

**81% of bleeds were controlled WITH 1 INFUSION.**

(n=70 bleeds)

**SELECTED IMPORTANT SAFETY INFORMATION**

**These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, or if bleeding is not controlled after using ELOCTATE.**

**Please see additional Important Safety Information and full Prescribing Information.**

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# ELOCTATE® SAFETY DATA FROM THE CLINICAL TRIALS

ELOCTATE has been evaluated for safety in 276 previously treated patients who received at least one dose in clinical studies (207 adults and adolescents and 69 children). 107 subjects were treated for at least 208 weeks.

ELOCTATE has also been evaluated for safety in 103 previously untreated patients who received at least one dose in clinical studies. Subjects were treated for a median of 64 weeks.

- Zero inhibitors were detected in clinical trials of previously treated patients (PTPs).
- In the adult study, 1 person had a transient, positive neutralizing antibody that was not confirmed upon repeat testing.
- In a clinical trial of previously untreated patients (PUPs), inhibitors were detected in:
  - 27% of patients (n=28/103)
  - 14% of patients (n=14/103) developed a high-titer inhibitors
- Formation of neutralizing antibodies (inhibitors) to factor VIII has been reported following administration of ELOCTATE

## ADVERSE REACTIONS

In the clinical studies of 276 previously treated people, adverse reactions occurred in 11 participants (4%). The most common adverse reactions were joint pain, general discomfort, muscle pain, headache and rash.

- Two subjects with cardiovascular risk factors each experienced a serious adverse reaction of myocardial infarction during the study

In the clinical studies of 103 previously untreated people, adverse reactions occurred in 29 (28%) patients. The most common adverse reactions were Factor VIII inhibitors, device-related blood clots and rash.



**INDICATION**

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**IMPORTANT SAFETY INFORMATION**

**Do not use ELOCTATE if you have had an allergic reaction to it in the past.**

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**Allergic reactions may occur with ELOCTATE. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.**

**Your body can also make antibodies called "inhibitors" against ELOCTATE, which may stop ELOCTATE from working properly.**

**Additional common side effects of ELOCTATE are headache, rash, joint pain, muscle pain and general discomfort.**

**If you have risk factors for developing abnormal blood clots in your body, such as an indwelling venous catheter, treatment with Factor VIII may increase this risk.**

**These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, or if bleeding is not controlled after using ELOCTATE.**

**MANUFACTURED BY**

Bioverativ Therapeutics Inc., Waltham, MA 02451 USA  U.S. License #2078

**Please see full Prescribing Information.**

ELOCTATE®
[Antihemophilic Factor (Recombinant), Fc Fusion Protein]

# DIG INTO THE DATA

**We know that some people like to nerd out on the facts. If that's your thing, then we've got a treat for you.**

## How our clinical studies were designed:

The efficacy of ELOCTATE has been studied longer than any other Factor VIII with an extended half-life. ELOCTATE was evaluated in previously treated patients with severe Hemophilia A in three clinical studies: A-LONG, Kids A-LONG, and ASPIRE extension study.

### A-LONG – 164 people (Ages 12-65)

In the A-LONG study, patients received ELOCTATE in one of three treatment arms:

- Individualized Prophylaxis: Every 3 to every 5 days (dose or interval could be adjusted to maintain appropriate FVIII levels)
- Weekly prophylaxis
- On-demand for bleeding episodes

### Kids A-LONG – 69 people (Ages 1-11)

In the Kids A-LONG study, patients received ELOCTATE in one treatment arm:

- Individualized Prophylaxis: Twice-weekly (dose or interval could be adjusted to maintain appropriate FVIII levels)

### ASPIRE – 211 people (Ages 1-65)

The ASPIRE extension study included people who completed A-LONG or Kids A-LONG

- 150 adults and adolescents 12 years and older
- 61 patients less than 12 years old

## Pharmacokinetics

The pharmacokinetics of ELOCTATE were evaluated following a single dose of 50 IU/kg in the Phase 3 study of 28 adult and 11 adolescent (ages 12-17), previously treated patients and in an open-label, multicenter study of 54 pediatric patients (ages 1-11). The adult subgroup included two adolescent subjects (a 15- and 16-year-old).

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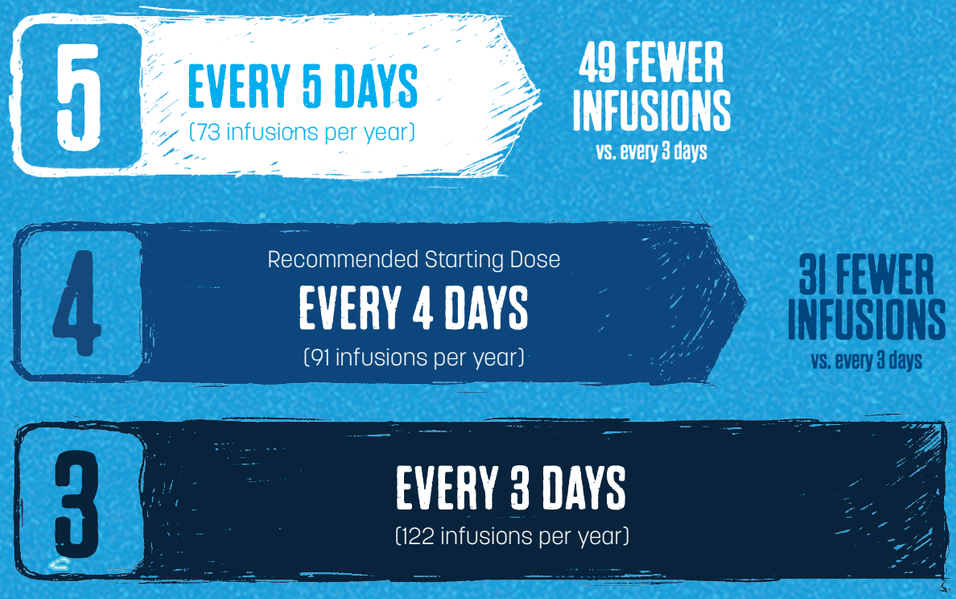
# NUMBERS YOU CAN COUNT ON

**98.8% of patients were able to dose less frequently with ELOCTATE than with their prior standard half-life treatment.**

Dosing

**With individualized dosing, ELOCTATE offers the potential for fewer infusions.**




**Calculated annual prophy infusions are based on recommended schedules.**

**Talk to your doctor to see what dosing option is right for you.**

**The recommended starting regimen is 50 IU/kg every 4 days as directed by your doctor. In children under 6 years of age, the recommended starting regimen is 50 IU/kg administered twice weekly. The regimen can be adjusted based on your body's individual response.**

**SELECTED IMPORTANT SAFETY INFORMATION**

**Do not use ELOCTATE if you have had an allergic reaction to it in the past.**

**Please see additional Important Safety Information and full Prescribing Information.**

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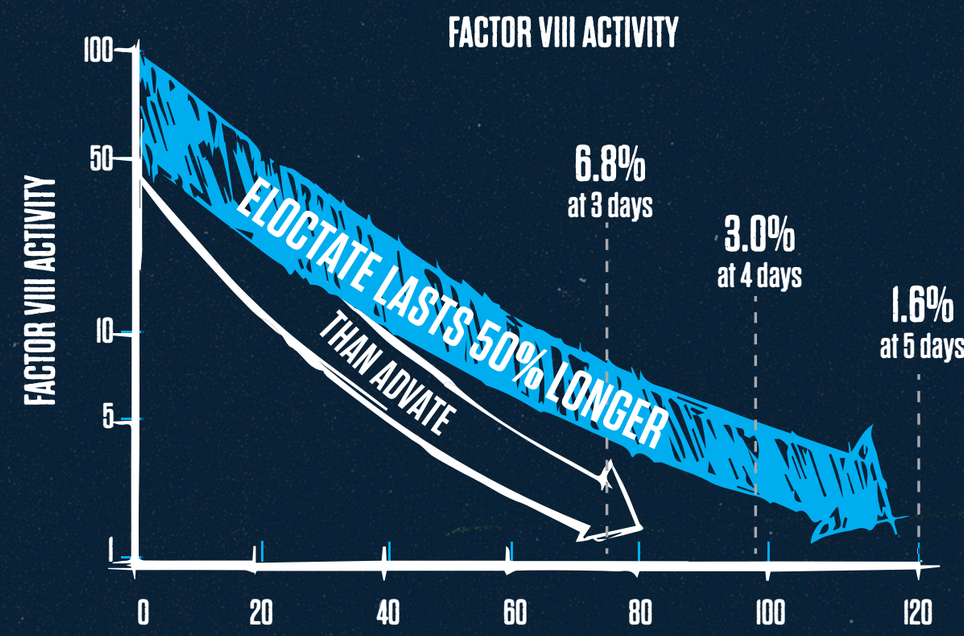
# SEE HOW WE STACK UP

**Learn why patients and their doctors count on ELOCTATE.**

Time in the Body

**In clinical studies, ELOCTATE was shown to last 50% longer in the body than ADVATE®.**



(n=28)

**Average half-life of ELOCTATE:**
12.7 hours in children ages 1 to 5 years
14.9 hours in children ages 6 to 11 years
16.4 hours in adolescents ages 12 to 17 years
19.7 hours in adults

**ADVATE® [Antihemophilic Factor (Recombinant)] is a registered trademark of Baxalta Incorporated, a Takeda company.**

**SELECTED IMPORTANT SAFETY INFORMATION**

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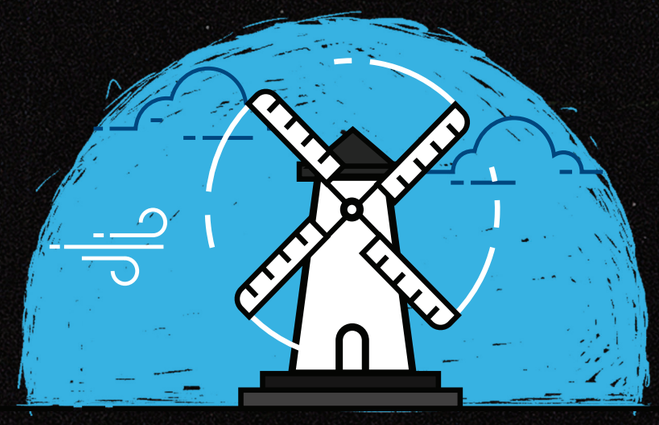
# Fc FUSION AND YOU

Fc Fusion

**Fc Fusion utilizes naturally occurring Fc receptors in your body to keep Factor VIII temporarily recirculating in your bloodstream.**

## Fc PROTEIN + FACTOR VIII = ELOCTATE

Just as the blades of a windmill harness naturally occurring wind to produce energy, Fc Fusion utilizes naturally occurring Fc receptors in your body to keep Factor VIII temporarily recirculating in your bloodstream. ELOCTATE is Factor VIII fused with an Fc protein.



We think the science of Fc Fusion is pretty cool. If you want to learn more about it, check out the card in the back pocket for the facts and figures.

**SELECTED IMPORTANT SAFETY INFORMATION**

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# MAKING DNA WORK FOR YOU

**We make ELOCTATE by producing Factor VIII using recombinant DNA technology. And we like to set the bar high.**

**Our manufacturing process is state of the art. Purification and viral standards are our main goal. We test ELOCTATE at every stage of the manufacturing process to ensure it meets strict quality standards.**

**SELECTED IMPORTANT SAFETY INFORMATION**

**Your body can also make antibodies called "inhibitors" against ELOCTATE, which may stop ELOCTATE from working properly.**

**Please see additional Important Safety Information and full Prescribing Information.**

Product Information

# VIAL SIZES TO FIT YOUR LIFE

**We offer the most vial strength options of any Factor VIII replacement therapy.**


Image not representative of actual drug product vials.

ELOCTATE is the only extended half-life therapy with 5000-IU and 6000-IU vial strengths. Having all these options means patients may be able to achieve their recommended dose with a single vial.*

Talk to your doctor to see what option may be best for you.

*Dosing and frequency may vary based on individual patient response.

ELOCTATE®
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# HEAR FROM REAL PATIENTS WHO COUNT ON ELOCTATE.

**Together with their doctors, over 2,500 patients have chosen to count on ELOCTATE. Which makes sense. After all, it's the #1 prescribed Factor VIII with an extended half-life.***

**Go to the next page to read interviews with people like you who've made the switch, and meet even more at ELOCTATE.com.†**

**SELECTED IMPORTANT SAFETY INFORMATION**

**Additional common side effects of ELOCTATE are headache, rash, joint pain, muscle pain and general discomfort.**

**Please see additional Important Safety Information and full Prescribing Information.**

***#1 prescribed based on HTC reported data as of [June 2020].**

**†Patient stories reflect the real-life experiences of persons diagnosed with hemophilia A who have been prescribed ELOCTATE. However, individual experiences may vary. Patient stories are not necessarily representative of what another person using ELOCTATE may experience.**

DJ, ELOCTATE Peer

Who's Made the Switch


DJ, on ELOCTATE

DJ

# MEET DJ

DJ is a guy who always marches to his own beat. Maybe that's why drums are his instrument of choice. As for his Factor VIII treatment, DJ and his doctor count on ELOCTATE and its proven record of bleed protection.

**So your name's DJ but you play the drums?**

Exactly. I like to keep people on their toes.

**Any other hobbies?**

I love comic books and I'm learning how to illustrate my own characters. It's a great creative outlet.

**What would your superpower be?**

Supersonic speed. Or maybe flight. I haven't decided.

**Speaking of decisions, how did you and your doctor decide on your current dosing regimen?**

When my doctor explained that the majority of bleeds occur in the joints, I knew I needed a treatment that I could count on to protect my joints from bleeds. My doctor helped me start on an every-4-day infusion routine with ELOCTATE. It's been great so far.

**What's next for you?**

Right now, I'm going with the flow. I may have hemophilia, but that does not mean I have to play quietly.

**Note:** This is a personal account of an ELOCTATE Peer. Please talk to your healthcare provider about whether ELOCTATE may be right for you. Individual results may vary.

The recommended starting regimen is 50 IU/kg every 4 days as directed by your doctor. In children under 6 years of age, the recommended starting regimen is 50 IU/kg administered twice weekly. The regimen can be adjusted based on your body's individual response.

**SELECTED IMPORTANT SAFETY INFORMATION**

If you have risk factors for developing abnormal blood clots in your body, such as an indwelling venous catheter, treatment with Factor VIII may increase this risk.

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Jonathan, on ELOCTATE

Jonathan

# MEET JONATHAN

Jonathan is widely known as “the car guy,” and rightly so. But when he’s not detailing a hot rod, he’s studying his hemophilia treatment. That’s how he learned about the importance of finding a treatment he can count on to protect him from bleeds.

**How long have you been working on cars?**

When I was a kid, my grandfather had a mechanic’s shop. I fell in love, and the rest is history.

**What was it about ELOCTATE that led you to switch from ADVATE®?**

What intrigued me was the extended half-life. I went from infusing every other day on ADVATE to working with my healthcare team to extend to every 5 days on ELOCTATE. But kinda like cars, each one of us is a different make, a different model, and requires different, specialized care. So all patients should speak with their doctor about their care.

**How’s it working out for you, so far?**

It’s great. What really helps me stay on track is knowing that that I can count on ELOCTATE to protect my joints from bleeds.

**So, what’s next for “the car guy”?**

I once built a car from scratch. It might be time for a new one.

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**SELECTED IMPORTANT SAFETY INFORMATION**

These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, or if bleeding is not controlled after using ELOCTATE.

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Paxton, on ELOCTATE

Jenny and Paxton

# MEET JENNY & PAXTON

Paxton is a little guy with big goals. That's because his mom, Jenny, has encouraged him to take ownership of his condition and be proactive with his factor treatment by choosing ELOCTATE.

**What attracted you to ELOCTATE?**

I was interested by ELOCTATE's extended half-life and how a Factor VIII, like ELOCTATE, can treat and prevent bleeds.

**How's he doing on ELOCTATE?**

We're so happy. He's always on the go, but since he's been on ELOCTATE, he's had no spontaneous bleeds. It's a comfort to know that his body and his joints–things that makes him active–are protected from bleeds as he grows up. But everyone is different.

**What's Paxton been up to lately?**

All sorts of stuff. He rides his bike. He's reading and doing math. He loves goofing around with his little sister.

**We heard he's a big swimmer too.**

Absolutely. He's like a dolphin when he gets into the pool. But really, every day he's trying something new. That's why his protection is so important to me.

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**SELECTED IMPORTANT SAFETY INFORMATION**

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ELOCTATE®
[Antihemophilic Factor (Recombinant), Fc Fusion Protein]

# START THE CONVERSATION. GET THE ANSWERS.

**No matter how you start the conversation with your healthcare team, you can count on these questions to help decide if ELOCTATE is right for you.**

Doctor Discussion Guide

**This discussion guide can help you have a productive chat about ELOCTATE.**

## QUESTIONS

- ☐ Why is it important to consider my joints in my treatment decisions?
- ☐ What are the potential benefits and risks for me and my joints in choosing a factor treatment like ELOCTATE?
- ☐ How does ELOCTATE work to protect me from bleeds and resolve my target joints?
- ☐ How does ELOCTATE work to improve my signs of bleeding and/or relieve pain?
- ☐ I've heard that the suggested prophylaxis starting regimen for ELOCTATE starts at 50 IU/kg every 4 days and may be adjusted to every 3 or 5 days. What would that mean for me?
- ☐ If I experience a breakthrough bleed after starting ELOCTATE, should I be worried? When should I call the doctor's office for follow up?
- ☐ Do you think that ELOCTATE is the right treatment for me for bleed and joint bleed protection?

The recommended starting regimen is 50 IU/kg every 4 days as directed by your doctor. In children under 6 years of age, the recommended starting regimen is 50 IU/kg administered twice weekly. The regimen can be adjusted based on your body's individual response.

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# WE'RE HERE TO HELP

**Learn about all the resources, support, and financial assistance options.**

## 1-855-MyELOCTATE (1-855-693-5628)

Available Monday through Friday 8:00 AM to 8:00 PM ET

Patient Services and Financial Support

### Free Trial Plus Program*

Receive your first 30-day supply of ELOCTATE immediately with a valid prescription from your healthcare provider. You may also be eligible to receive free factor for a limited period of time, while Patient Services addresses your factor access issue.

### Copay Program*

New to ELOCTATE? Already on ELOCTATE? The copay program offers up to $20,000 of co-payment or co-insurance coverage for your ELOCTATE prescription. Best of all, there are no income requirements or caps, so you can get started with your treatment right away.

### Factor Access Program*

Helps you access ELOCTATE, even if your insurance coverage is interrupted–for example, you are between jobs or changing insurers.

### MicroHealth

Sign up for MicroHealth to stay on top of your hemophilia information on your computer or phone. Get text reminders, track your infusions and bleeds, scan barcodes to track your factor, and access records on the go.

*Not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DoD, TRICARE, or similar federal or state programs including any state pharmaceutical assistance programs. Not valid where prohibited by law. Sanofi Genzyme reserves the right to modify or discontinue the programs at any time. Savings may vary depending on patients' out-of-pocket costs. All program details provided upon registration. Please visit ELOCTATE.com for more information.

MicroHealth is a health network for chronic care. Sanofi Genzyme does not have access to any of your personal information collected by MicroHealth.

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# COUNT ON YOUR LOCAL CORE

**If you find yourself with questions about ELOCTATE or seeking additional resources, CoRes or Community Relations and Education Managers are here to make sure you can navigate the process with ease. They're not just experts on ELOCTATE, they're people with a real connection to the hemophilia community. No matter where or when, they're always a call or click away.**

**Dedicated**

CoRe Managers are dedicated to helping others in the hemophilia community.

**Understanding**

CoRe Managers are your advocates. They are people with decades of experience dealing with hemophilia, who understand and appreciate the community's needs.

**Accessible**

Your CoRe prioritizes face-to-face conversations to get to know you. They're just a phone call, text, or email away.

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# THAT'S WHY YOU NEED A FACTOR VIII TREATMENT YOU CAN COUNT ON.

**Now you're all caught up on ELOCTATE and ready to start your next chapter. Talk to your doctor, write down questions for your healthcare team, visit ELOCTATE.com, or contact your CoRe for more information. And remember, you use your joints more than you think. That's why you need a Factor VIII treatment you can count on.**

**And if you're looking for more ELOCTATE info, check out the Science of Fc Fusion. It's all here.**

**Please see additional Important Safety Information and full Prescribing Information.**

SANOFI GENZYME

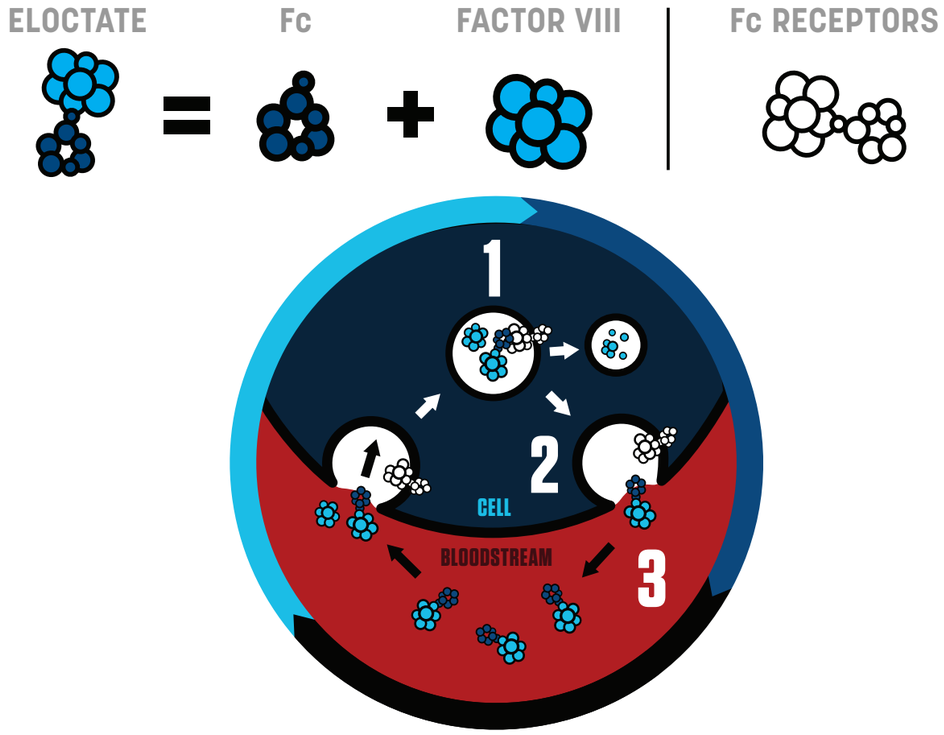


MAT-US-2003326-v2.0-01/2021

ELOCTATE®
[Antihemophilic Factor
(Recombinant), Fc Fusion Protein]

# SEE Fc FUSION IN ACTION

**ELOCTATE is Factor VIII fused with an Fc protein. Fc receptors exist naturally in your body.**




### 1. BIND
Naturally produced Factor VIII flows through the bloodstream and enters cells within your body; eventually breaking down.

The Fc portion of ELOCTATE allows it to bind with an Fc receptor already in your body.

### 2. REDIRECT
The binding with Fc receptor redirects ELOCTATE back towards the bloodstream to protect ELOCTATE from being broken down inside the cell.

### 3. RECIRCULATE
By using the natural Fc process, ELOCTATE is able to recirculate in the body longer. Eventually ELOCTATE is broken down, but without Fc Fusion, it wouldn't be able to recirculate in the bloodstream to extend the time ELOCTATE is in the body.

## INDICATION

ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] is an injectable medicine that is used to help control and prevent bleeding in people with Hemophilia A (congenital Factor VIII deficiency). Your healthcare provider may give you ELOCTATE when you have surgery.

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Do not use ELOCTATE if you have had an allergic reaction to it in the past.

Tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines, have any allergies, are breastfeeding, are pregnant or planning to become pregnant, or have been told you have inhibitors (antibodies) to Factor VIII.

Allergic reactions may occur with ELOCTATE. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.

Your body can also make antibodies called "inhibitors" against ELOCTATE, which may stop ELOCTATE from working properly.

Additional common side effects of ELOCTATE are headache, rash, joint pain, muscle pain and general discomfort.

If you have risk factors for developing abnormal blood clots in your body, such as an indwelling venous catheter, treatment with Factor VIII may increase this risk.

These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, or if bleeding is not controlled after using ELOCTATE.

**Please see additional Important Safety Information and full Prescribing Information.**