# SPLENDIDLY SIMILAR





FDA-approved biosimilar to Soliris®



Taken the same way as Soliris



Savings program







#### IMPORTANT SAFETY INFORMATION

What is the most important information I should know about EPYSQLI® (eculizumab-aagh)? EPYSQLI is a medicine that affects your immune system. EPYSQLI may lower the ability of your immune system to fight infections.

- EPYSQLI increases your chance of getting serious meningococcal infections caused by Neisseria meningitidis bacteria. Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.
  - You must complete or update your meningococcal vaccines at least 2 weeks before your first dose of EPYSQLI.
  - If you have not completed your meningococcal vaccines and EPYSQLI must be started right away, you should receive the required vaccine(s) as soon as possible.
  - If you have not been vaccinated and EPYSQLI must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
  - If you had a meningococcal vaccine in the past, you might need additional vaccines before starting EPYSQLI. Your healthcare provider will decide if you need additional meningococcal vaccines.
  - Meningococcal vaccines do not prevent all meningococcal infections. Call your healthcare provider
    or get emergency medical care right away if you get any of these signs and symptoms of a serious
    meningococcal infection. Fever, fever with high heart rate, headache and fever, confusion, muscle
    aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a
    stiff neck or stiff back or eyes sensitive to light.





# WHAT IS EPYSQLI®?

EPYSQLI is an FDA-approved biosimilar that can be taken in place of Soliris<sup>®</sup>, whether you're new to therapy or currently taking Soliris.

## What is a biosimilar?



A biosimilar is an FDA-approved version of an original biologic designed to offer the same treatment benefits.

 The FDA makes sure biosimilars are as safe and effective as the original biologic by approving biosimilars after a careful review of data, studies, and tests

EPYSQLI has been carefully tested and is approved by the FDA as a biosimilar to Soliris

## How are EPYSQLI and Soliris alike?



EPYSQLI and Soliris are made in the same way



EPYSQLI and Soliris have similar treatment benefits and risks



EPYSQLI and Soliris are given the same way

## **IMPORTANT SAFETY INFORMATION (cont'd)**

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last dose of EPYSQLI. Your risk of meningococcal infection may continue for several weeks after your last dose of EPYSQLI. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.



# WHAT DOES EPYSQLI® DO?

**EPYSQLI** is used to treat these same conditions as Soliris®

## Paroxysmal nocturnal hemoglobinuria (PNH)

People with paroxysmal nocturnal hemoglobinuria

# Atypical hemolytic uremic syndrome (aHUS)

People with atypical hemolytic uremic syndrome
• EPYSQLI is not for use in treating people with Shiga toxin *E coli*—related hemolytic uremic syndrome (STEC-HUS)

# Generalized myasthenia gravis (qMG)

Adults with generalized myasthenia gravis who are anti-acetylcholine receptor (AchR) antibody positive

It is not known if EPYSQLI is safe and effective in children with PNH or gMG.

EPYSQLI can be taken in place of Soliris for any of the conditions above

## IMPORTANT SAFETY INFORMATION (cont'd)

EPYSQLI is only available through a program called the EPYSQLI Risk Evaluation and Mitigation Strategy (REMS). Before you can receive EPYSQLI, your healthcare provider must:

- enroll in the EPYSQLI REMS program
- counsel you about the risk of serious meningococcal infections
- give you information about the signs and symptoms of serious meningococcal infection
- make sure that you are vaccinated against serious infections caused by meningococcal bacteria
  and that you receive antibiotics if you need to start EPYSQLI right away and you are not up to
  date on your vaccines
- give you a Patient Safety Card about your risk of meningococcal infection, as discussed above



# **RECEIVING EPYSQLI®**

## **Before treatment**

You must complete or update your meningococcal vaccinations at least 2 weeks before your first dose of EPYSQLI



Your healthcare provider will talk to you about the risks, signs, and symptoms of serious meningococcal infection and give you a **Patient Safety Card**.

- Carry your Patient Safety Card with you at all times during treatment, and for 3 months after your final dose of EPYSQLI
- Tell your healthcare provider about all your medical conditions and all the medicines you take
- Make sure to read the <u>Medication Guide</u> before receiving EPYSQLI

**EPYSQLI** is given by intravenous (IV) infusion. Where you receive EPYSQLI can depend on your insurance and where you live.

**Teva Shared Solutions® for Biosimilars** offers a range of services, including understanding insurance benefits and financial assistance.

Your healthcare provider will enroll you in Teva Shared Solutions before you receive EPYSQLI

A Teva Shared Solutions representative will contact you to guide you through your treatment journey

## IMPORTANT SAFETY INFORMATION (cont'd)

**EPYSQLI may also increase the risk of other types of serious infections** caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*.

- If your child is treated with EPYSQLI, your child should receive vaccines against *Streptococcus* pneumoniae and *Haemophilus influenzae type b* (Hib).
- Certain people may be at risk of serious infections with gonorrhea. Talk to your healthcare
  provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and
  regular testing.
- Certain fungal infections (aspergillus) may also happen if you take EPYSQLI and have a weak immune system or a low white blood cell count.

For more information about side effects, see "What are the possible side effects of EPYSQLI?"



# **RECEIVING EPYSQLI®**

## **During treatment**

Keep track of your appointments. Adults usually receive EPYSQLI once a week for 5 weeks, and every 2 weeks after that.

If you are receiving EPYSQLI at an infusion center:



Arrive early, leaving yourself time for necessary paperwork



Wear comfortable clothes. Consider bringing a sweater or blanket to keep warm.



Bring something to pass the time like a book, podcast, or other activity

Expect your infusions to take about 35 minutes.

In children, infusions usually take 1-4 hours

After each infusion, your healthcare provider will monitor you for at least 1 hour for infusion-related reactions.

 Tell your healthcare provider right away if you have chest pain, shortness of breath, swelling of your face, tongue, or throat, feel faint, or pass out during your infusion

If you miss an EPYSQLI infusion, call your healthcare provider right away.

Call your healthcare provider or get emergency medical care right away if you get any of the signs and symptoms of a serious meningococcal infection.

#### IMPORTANT SAFETY INFORMATION (cont'd)

Who should not receive EPYSQLI?

**Do not receive EPYSQLI if you** have a serious meningococcal infection when you are starting EPYSQLI treatment.

Before you receive EPYSQLI, tell your healthcare provider about all of your medical conditions, including if you have an infection or fever, are pregnant or plan to become pregnant. It is not known if EPYSQLI will harm your unborn baby or are breastfeeding or plan to breastfeed. It is not known if EPYSQLI passes into your breast milk.

**Tell your healthcare provider about all the medicines you take,** including prescription and overthe-counter medicines, vitamins, and herbal supplements. EPYSQLI and other medicines can affect each other causing side effects.

Know the medications you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

If you miss an EPYSQLI infusion, call your healthcare provider right away.



#### What is EPYSOLI?

EPYSQLI is a prescription medicine used to treat:

- people with paroxysmal nocturnal hemoglobinuria (PNH).
- people with atypical hemolytic uremic syndrome (aHUS).
  - EPYSQLI is not for use in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive.

It is not known if EPYSQLI is safe and effective in children with PNH or gMG.

#### IMPORTANT SAFETY INFORMATION

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

EPYSQLI is a medicine that affects your immune system. EPYSQLI may lower the ability of your immune system to fight infections.

- EPYSQLI increases your chance of getting serious meningococcal infections caused by Neisseria
  meningitidis bacteria. Meningococcal infections may quickly become life-threatening or cause death if
  not recognized and treated early.
  - You must complete or update your meningococcal vaccines at least 2 weeks before your first dose of EPYSQLI.
  - If you have not completed your meningococcal vaccines and EPYSQLI must be started right away, you should receive the required vaccine(s) as soon as possible.
  - If you have not been vaccinated and EPYSQLI must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
  - If you had a meningococcal vaccine in the past, you might need additional vaccines before starting EPYSQLI. Your healthcare provider will decide if you need additional meningococcal vaccines.
  - Meningococcal vaccines do not prevent all meningococcal infections. Call your healthcare provider
    or get emergency medical care right away if you get any of these signs and symptoms of a serious
    meningococcal infection. Fever, fever with high heart rate, headache and fever, confusion, muscle
    aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a
    stiff neck or stiff back or eyes sensitive to light.

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last dose of EPYSQLI. Your risk of meningococcal infection may continue for several weeks after your last dose of EPYSQLI. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.



#### IMPORTANT SAFETY INFORMATION (cont'd)

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- give you information about the signs and symptoms of serious meningococcal infection
- make sure that you are vaccinated against serious infections caused by meningococcal bacteria and that you receive antibiotics if you need to start EPYSQLI right away and you are not up to date on your vaccines
- give you a Patient Safety Card about your risk of meningococcal infection, as discussed above

**EPYSQLI may also increase the risk of other types of serious infections** caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*.

- If your child is treated with EPYSQLI, your child should receive vaccines against *Streptococcus* pneumoniae and *Haemophilus influenzae type b* (Hib).
- Certain people may be at risk of serious infections with gonorrhea. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea infection, about gonorrhea prevention, and regular testing.
- Certain fungal infections (aspergillus) may also happen if you take EPYSQLI and have a weak immune system or a low white blood cell count.

For more information about side effects, see "What are the possible side effects of EPYSQLI?"

#### Who should not receive EPYSQLI?

**Do not receive EPYSQLI if you** have a serious meningococcal infection when you are starting EPYSQLI treatment.

Before you receive EPYSQLI, tell your healthcare provider about all of your medical conditions, including if you have an infection or fever, are pregnant or plan to become pregnant. It is not known if EPYSQLI will harm your unborn baby or are breastfeeding or plan to breastfeed. It is not known if EPYSQLI passes into your breast milk.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. EPYSQLI and other medicines can affect each other causing side effects.

Know the medications you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

If you miss an EPYSQLI infusion, call your healthcare provider right away.



## IMPORTANT SAFETY INFORMATION (cont'd)

If you have PNH, your healthcare provider will need to monitor you closely for at least 8 weeks after stopping EPYSQLI. Stopping treatment with EPYSQLI may cause breakdown of your red blood cells due to PNH. Symptoms or problems that can happen due to red blood cell breakdown include:

- drop in the number of your red blood cell count
- drop in your platelet
   confusion counts
- chest pain

- difficulty breathing
- kidney problems
- blood clots

If you have aHUS, your healthcare provider will need to monitor you closely for at least 12 weeks after stopping EPYSQLI for signs of worsening aHUS symptoms or problems related to abnormal clotting (thrombotic microangiopathy). Symptoms or problems that can happen with abnormal clotting may include:

stroke

- kidney problems
- difficulty breathing
- chest pain (angina)

- confusion
- seizure

- swelling in arms or legs
- a drop in your platelet count

## What are the possible side effects of EPYSQLI?

## EPYSQLI can cause serious side effects including:

See "What is the most important information I should know about EPYSQLI?"

Serious infusion-related reactions can happen during your EPYSQLI infusion.

Tell your healthcare provider or nurse right away if you experience chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat or feel faint or pass out during your EPYSQLI infusion.

If you have an infusion-related reaction to EPYSQLI, your healthcare provider may need to infuse EPYSQLI more slowly, or stop EPYSQLI.

The most common side effects in people with PNH treated with EPYSQLI include:

headache, pain or swelling of your nose or throat (nasopharyngitis), back pain and nausea.

## The most common side effects in people with aHUS treated with EPYSQLI include:

Headache, diarrhea, high blood pressure (hypertension), common cold (upper respiratory infection), stomach-area (abdominal) pain, vomiting, pain or swelling of your nose or throat (nasopharyngitis), low red blood cell (anemia), cough, swelling of legs or feet (peripheral edema), nausea, urinary tract infections and fever

The most common side effects in people with gMG treated with EPYSQLI include: muscle and joint (musculoskeletal) pain

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of EPYSQLI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

# WE'RE HERE FOR YOU



## Eligible patients may pay as little as \$0 for EPYSQLI®

- Offer is available for patients with commercial insurance only
- Offer is NOT available for patients eligible for Medicare, Medicaid, or any other form of government insurance coverage

# Teva Shared Solutions® for Biosimilars offers a range of support services

A Teva Shared Solutions representative will contact you to guide you through your treatment journey

## IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of EPYSQLI?

EPYSQLI can cause serious side effects including:

See "What is the most important information I should know about EPYSQLI?"

Serious infusion-related reactions can happen during your EPYSQLI infusion.

Tell your healthcare provider or nurse right away if you experience chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat or feel faint or pass out during your EPYSQLI infusion.

If you have an infusion-related reaction to EPYSQLI, your healthcare provider may need to infuse EPYSQLI more slowly, or stop EPYSQLI.

The most common side effects in people with PNH treated with EPYSQLI include:

headache, pain or swelling of your nose or throat (nasopharyngitis), back pain and nausea.

The most common side effects in people with aHUS treated with EPYSQLI include:

Headache, diarrhea, high blood pressure (hypertension), common cold (upper respiratory infection), stomach-area (abdominal) pain, vomiting, pain or swelling of your nose or throat (nasopharyngitis), low red blood cell (anemia), cough, swelling of legs or feet (peripheral edema), nausea, urinary tract infections and fever

The most common side effects in people with gMG treated with EPYSQLI include: muscle and joint (musculoskeletal) pain

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of EPYSQLI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see Important Safety Information throughout and read the Medication Guide in the full <u>Prescribing Information</u>, including Boxed Warning.

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