

INDICATION

What is CABLIVI?



adults with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

SELECT IMPORTANT SAFETY INFORMATION

Who should not take CABLIVI?

Do not take CABLIVI if you've had an allergic reaction to caplacizumab-yhdp or to any of the ingredients in CABLIVI.

Please see Important Safety Information and full Prescribing Information.

WHAT IS aTTP?

aTTP is a serious condition that can be managed if treated as soon as possible

Thrombotic thrombocytopenic purpura (TTP) is a rare, life-threatening blood disorder that causes small blood clots throughout the body. There are 2 types of TTP: acquired TTP (aTTP) and inherited TTP. 95% of all TTP cases are aTTP.

aTTP is a lifelong condition. Some people may only experience 1 episode of aTTP. However, most people have additional aTTP episodes, called "relapses," over their lifetime.

To understand aTTP, you need to understand the roles of vWF and ADAMTS13

- von Willebrand factor (vWF) is an important part of your blood. It is made of strands that attract platelets to make blood clots to prevent bleeding
- Platelets are small cells in your blood. Their main job is to stick to areas of injury and form blood clots that help stop bleeding
- ADAMTS13 is a protein in your blood. It keeps vWF strands from growing too long by cutting the strands into small pieces
- If you have a deficiency in ADAMTS13, the vWF strands stay too long, attracting a lot of platelets, and form clots that you don't need. These clots may become dangerous to your health

When you have aTTP, your immune system attacks ADAMTS13. Because of this, your blood doesn't have enough ADAMTS13 to cut the vWF strands. The strands keep growing and attract platelets. which can form dangerous clots.

WHAT CAUSES TTP?

It's not fully understood why some people develop TTP. However, some things can be potential risk factors for TTP. These risks include:



Certain conditions, including cancer, HIV, lupus, infections, or pregnancy



Surgery or other medical procedures



Some medicines, including chemotherapy and hormone therapy



Certain estrogenbased medicines (birth control pills)

aTTP CAUSES 3 THINGS TO GO WRONG IN YOUR BODY



Problem caused by aTTP

Your immune system attacks

What this means for your body

If ADAMTS13 is being attacked, you ADAMTS13 with autoantibodies won't have enough of it in your blood

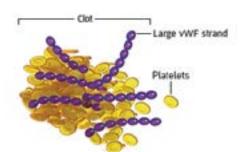


Problem caused by aTTP

ADAMTS13, vWF strands don't get cut

What this means for your body

Because you don't have enough When vWF strands stay too long, they attract a lot of platelets when they're not supposed to, which means you won't have enough platelets in your blood



Problem caused by aTTP

When long strands of vWF attract platelets, blood clots form in small arteries where you don't need them

What this means for your body

These blood clots can be dangerous and may cause serious health problems like stroke, heart attack, seizures, and organ damage

TREATING aTTP

CABLIVI IS RECOMMENDED BY EXPERTS



The goal of treatment is to address each problem aTTP causes in your body.

3 therapies to potentially address the 3 problems caused by aTTP

Problem caused by aTTP Your immune system attacks



Treatment

Immunosuppressive therapy suppresses the production of anti-ADAMTS13 autoantihodies

Problem caused by aTTP

Because you don't have enough ADAMTS13. vWF strands don't get cut. When vWF strands remain too long, they start to attract more platelets, which means you won't have enough platelets in your blood

form when you don't need them

ADAMTS13 with autoantibodies



Treatment

Plasma exchange (PEX) replaces platelets and ADAMTS13 in your blood

Problem caused by aTTP





Treatment

CABLIVI inhibits dangerous clots from forming by attaching to vWF so platelets can't

CABLIVI is a breakthrough treatment that helps in the fight against aTTP and is designed to prevent dangerous blood clots.

CABLIVI is the only FDA-approved treatment for aTTP in combination with PEX and immunosuppression recommended by the ISTH*



- The International Society on Thrombosis and Haemostasis (ISTH) Treatment Guidelines suggest using CABLIVI for patients experiencing their first episode or another aTTP episode
- The ISTH created a guideline for the treatment of TTP, including aTTP
- The guideline helps doctors and other healthcare professionals to make informed treatment decisions for patients with aTTP
- The ISTH is a global, not-for-profit organization of experts in this field. It has more than 5000 members in 100 countries

SELECT IMPORTANT SAFETY INFORMATION

What should I tell my healthcare team before starting CABLIVI?

Tell your doctor if you have a medical condition including if you have a bleeding disorder. Tell your doctor about any medicines you take, including medicines that increase your risk of bleeding such as anti-coagulants and anti-platelet agents.

Talk to your doctor before scheduling any surgery, medical or dental procedure.

Please see Important Safety Information and full Prescribing Information.

^{*}Recommendations based on laboratory testing and diagnosis.



CABLIVI CONFIDENCE

POSSIBLE SIDE EFFECTS WITH CABLIVI



CABLIVI with PEX and immunosuppressive therapy was shown to provide better results in aTTP

CABLIVI was tested in a clinical study of 145 adults with aTTP



72 people were given CABLIVI and PEX and immunosuppressive therapy





73 people were given a placebo (an injection without any medicine) and PEX and immunosuppressive therapy

During PEX 30 days after PEX Additional treatment time

Both groups received either CABLIVI or placebo after their daily PEX, and then for 30 days after

Some people received more treatment (up to 28 additional days) based on their doctor's decision

After treatment was stopped, everyone was followed by their doctor for 28 more days.

In the clinical study, the CABLIVI difference was clear



CABLIVI helped return platelet counts to normal significantly faster

when added to PEX and immunosuppressive therapy

REQUIRING RESTARTING PEX **DURING TREATMENT AND FOR 28 DAYS AFTER**

67% fewer patients relapsed while taking CABLIVI, where a drop in platelets required restarting PEX, during treatment and for 28 days after

Significantly fewer people had another episode of aTTP that required starting PEX again within the full study period (while taking CABLIVI and 28 days after stopping CABLIVI) in the CABLIVI group vs the placebo group: 13% receiving CABLIVI (9 people) vs 38% receiving placebo (28 people).

CABLIVI can cause side effects, although not everyone will experience them. Because CABLIVI works by inhibiting the formation of blood clots, it may affect normal blood clotting and increase the risk of severe bleeding. Contact your doctor immediately if excessive bleeding or bruising happens. Your doctor will decide on next steps.

CABLIVI side effects may include:

- Bleeding from gums
- Muscle pain
- Nosebleeds
- Rash
- Headache
- Blood in urine
- Anal bleeding

- Unusually heavy periods
- Hemorrhoids
- Vaginal bleeding
- Fever
- Shortness of breath
- Tiredness
- Injection site reactions such as rash, bleeding, and itching

Please see the full list of side effects within the full Prescribing Information for CABLIVI. Talk with your doctor if you have any questions or if you have a side effect that does not go away.



Reporting side effects

If you have side effects, including ones not listed above, talk to your doctor right away. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

SELECT IMPORTANT SAFETY INFORMATION What are the possible side effects of CABLIVI?

CABLIVI can cause severe bleeding. In clinical studies, severe bleeding adverse reactions of nosebleed, bleeding from the gums, bleeding in the stomach or intestines, and bleeding from the uterus were each reported in 1% of subjects. In the post-marketing setting, cases of life-threatening and fatal bleeding were reported in patients receiving CABLIVI. Contact your doctor immediately if symptoms of excessive bruising, excessive bleeding, or major bleeding occur. Signs and symptoms of bleeding include: pain, swelling or discomfort, prolonged bleeding from cuts, increased menstrual flow or vaginal bleeding, nosebleeds, bleeding of gums from brushing, unusual bleeding or bruising, red or dark brown urine, red or tar black stools, headache, dizziness, or weakness.

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CABLIVI CONFIDENCE IN PEOPLE LIVING WITH aTTP



Alex, real CABLIVI user





Heather, real CABLIVI user



"Relapsing 4 or 5 times in 1 year—that was difficult on my body. Difficult on my family. Difficult on my emotions... My doctor and I had talked about CABLIVI and thought that I should give it a shot."



Watch Heather's story

Watch Alex's story

" My main concern was bringing up my platelet counts.

So learning that CABLIVI, along with immunosuppressive therapy and plasma exchange, could help bring my platelet count to a normal level faster, it's like, 'Okay, let's do this.'"

Every patient's experience with CABLIVI is unique, and individual results will vary. If you're interested in learning more, please speak with your doctor about the potential benefits and risks of treatment with CABLIVI and whether CABLIVI may be right for you.

Alex and Heather are being compensated by Sanofi.

SELECT IMPORTANT SAFETY INFORMATION (CONT'D) What are the possible side effects of CABLIVI? (cont'd)

You may have a higher risk of bleeding if you have a bleeding disorder (i.e. hemophilia) or if you take other medicines that increase your risk of bleeding such as anti-coagulants and anti-platelet agents.

CABLIVI should be stopped for 7 days before surgery or any medical or dental procedure. Talk to your doctor before you stop taking CABLIVI.

Please see Important Safety Information and <u>full Prescribing Information</u>.



TAKING CABLIVI

Cablivi: caplacizumab-yhdp

CABLIVI AT HOME

CABLIVI treatment starts in the hospital. After you leave the hospital, CABLIVI treatment continues at home.

CABLIVI treatment timeline



You start CABLIVI at the same time as PEX

- Your first dose of CABLIVI is given through an IV before your first PEX treatment; then, when your first PEX treatment is finished, you will get an injection of CABLIVI
- From then on, CABLIVI is given as an injection. You will get CABLIVI every day after your PEX



After your last PEX, CABLIVI treatment continues for 30 days

 When your doctor decides you can go home, you will continue your CABLIVI injections at home every day

Your doctor may decide you need to take CABLIVI for more than 30 days

- This additional period may last up to 28 days
- Your doctor may order additional blood tests, including a test to measure your ADAMTS13 level. This test may help your doctor decide when you no longer need CABLIVI

Continue taking CABLIVI until your doctor tells you to stop.

It's important to continue the full course of your treatment to help prevent another episode of aTTP. CABLIVI is recommended to be taken for 30 days after finishing PEX. Some people may need to take CABLIVI longer, depending on their doctor's direction. Always talk to your doctor before making treatment decisions, and do not stop treatment on your own, even if you start to feel better.

Helpful resources for self-administration of CABLIVI

Your CABLIVI injection can be done by you, a family member, or another
caregiver. You and your doctor should decide who that person will be. The
person who is giving CABLIVI should receive training from your doctor or
nurse until they feel confident. Let your doctor know if you, your family member,
or your caregiver are not comfortable doing this, or if you have any questions



 You can view a helpful video and download the CABLIVI Administration Training Guide at:
 CABLIVI.com/attp/how-to-take-cablivi





- Clinical educators* are part of CABLIVI Patient Solutions and provide support to people taking CABLIVI after they leave the hospital
- Call **1-855-724-7222**, Monday through Friday, 8 AM to 8 PM ET, to learn how a clinical educator can help with administering CABLIVI, setting up a treatment plan, and answering questions

What if I miss a dose of CABLIVI?

Taking CABLIVI once a day for 30 days after you stop PEX is important for your treatment. However, if you miss a dose, do the following:

• Take CABLIVI within 12 hours of your scheduled time. After 12 hours, skip the dose and take the next scheduled dose

SELECT IMPORTANT SAFETY INFORMATION (CONT'D) What are the possible side effects of CABLIVI? (cont'd)

The most common side effects include nosebleed, headache and bleeding gums.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of CABLIVI. Call your doctor for medical advice about side effects.

Please see Important Safety Information and full Prescribing Information.

^{*}CABLIVI clinical educators are paid to provide educational services on behalf of Sanofi. They don't provide medical advice. You should always talk to your doctor about any healthcare needs.



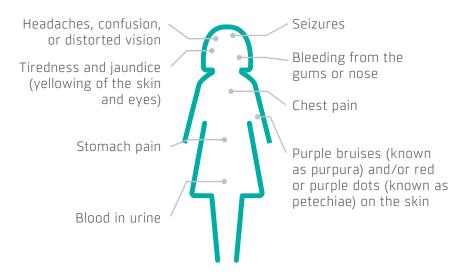
MONITORING FOR aTTP SYMPTOMS



aTTP is a lifelong condition. Everyone's experience with aTTP is different. While some people may only experience 1 aTTP episode, others may have more. In fact, up to 90% of people who have 1 aTTP episode will have another over their lifetime.

It's important to watch for the return of any aTTP symptoms. These could be a warning of another aTTP episode.

aTTP symptoms can include:





If you think that you are having symptoms of an aTTP episode, talk to your doctor or visit your local emergency room right away.

CHECKING IN WITH YOUR DOCTOR

Your doctor will likely want to see you regularly to check that CABLIVI is working for you. It's important that you go to all follow-up appointments because your doctor may need to make changes to your treatment. Follow-up appointments are also a good time for you to ask questions. You can also let your doctor know about any side effects you may have experienced, even those that may not seem serious.

Tell your doctor if:

- You bleed excessively during treatment. Your doctor may ask you to stop treatment, and they will decide when you can start again
- You are using blood thinners (for example, heparin, warfarin, rivaroxaban, apixaban)
- You have a bleeding disorder such as hemophilia. Your doctor will decide how you should be treated
- You have a history of liver issues
- You are going to have an operation or dental treatment. Your doctor may advise you to postpone or stop CABLIVI before your surgery or dental work



Questions about CABLIVI

You can download a Doctor Discussion Guide from CABLIVI.com/Content/assets/attp-pdf-assets/CABLIVI-Doctor-Discussion-Guide.pdf. This guide can help you take an active role in managing your treatment and gives you some suggested questions to ask your doctor.

Talking about your mental health

aTTP usually comes on suddenly. The symptoms can be very serious and scary, and the process of getting diagnosed may be stressful. It's very common to experience a number of emotions during and after an aTTP episode, from frustration to worry to depression.

If you have aTTP, talking with your doctor about your mental and emotional health is as important as checking in about your physical health. Be open and honest about what you're experiencing. Your doctor may recommend some lifestyle changes to help you feel your best. If you're suffering from clinical depression or anxiety, your doctor will make sure you get any treatment, help, and support you need.

Please see Important Safety Information and <u>full Prescribing Information</u>.

SUPPORT AND RESOURCES

INDICATION AND IMPORTANT SAFETY INFORMATION



CABLIVI Patient Solutions

CABLIVI Patient Solutions is a program that provides guidance and support throughout your journey, from hospital to home. The services offered by CABLIVI Patient Solutions include:



Specialty pharmacy services



Support from clinical educators around taking CABLIVI at home



Financial assistance for eligible patients*

To learn more, call **1-855-724-7222**, Monday through Friday, 8 AM to 8 PM ET.

*Approval is not guaranteed. Sanofi reserves the right to modify or discontinue the programs at any time. Additional terms and conditions apply.

TEMs are here to support you

A rare disease often comes with a lot of questions. The Therapeutic Education Managers (TEMs)† can help you navigate your experience with aTTP. They can also help you learn more about aTTP so you can have informed and productive conversations with your doctor. Contact CABLIVI Patient Solutions to learn more.

†TEMs are paid to provide educational services on behalf of Sanofi. They don't provide medical advice. You should always talk to your doctor about any healthcare needs.

The aTTP community

A number of advocacy groups support people living with aTTP and their families. Some organizations that may be helpful to you are:

Answering T.T.P. Foundation

A Canadian advocacy and support group for all people living with TTP, caring for someone with TTP, or treating TTP.

answeringttp.org

National Organization for Rare Disorders (NORD)

A patient advocacy organization dedicated to people with rare diseases and the organizations that serve them.

rarediseases.org

The Ree Wynn Foundation

A foundation in the United States whose mission is to provide education and promote awareness of TTP.

reewynn.org

What is CABLIVI?

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You may have a higher risk of bleeding if you have a bleeding disorder (i.e. hemophilia) or if you take other medicines that increase your risk of bleeding such as anti-coagulants and anti-platelet agents.

CABLIVI should be stopped for 7 days before surgery or any medical or dental procedure. Talk to your doctor before you stop taking CABLIVI.

The most common side effects include nosebleed, headache and bleeding gums.

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This listing is provided as a resource only and does not constitute an endorsement by Sanofi of any particular organization or its programming. Additional resources on this topic may be available and should be investigated. Sanofi does not review or control the content of non-Sanofi websites.

Please see <u>full Prescribing Information</u>.



CABLIVI IS A BREAKTHROUGH TREATMENT THAT HELPS IN THE FIGHT AGAINST ATTP



FIRST AND ONLY FDA-APPROVED TREATMENT FOR aTTP

CABLIVI is the first and only FDA-approved treatment for adults with aTTP when used in combination with PEX and immunosuppressive therapy



ADDED CONFIDENCE AGAINST aTTP

CABLIVI helped return platelet counts to normal faster, and people had fewer relapses, when CABLIVI was added to PEX and immunosuppressive therapy in a clinical study vs PEX and immunosuppressive therapy alone



ONGOING SUPPORT

CABLIVI Patient Solutions helps you transition from hospital to home with personalized support, education, and training

Take CABLIVI exactly as your doctor prescribes, even if you start to feel better.

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Learn more about how you can take on aTTP with CABLIVI CONFIDENCE at CABLIVI.com.

