Be prepared to make the best decision about Activase (t-PA) for acute ischemic stroke

If you or a family member are having an ischemic stroke, you may be eligible for treatment with Activase (t-PA).

The information in this booklet can help you make this important treatment decision with your doctor.

This booklet does not list all the benefits and risks of Activase (t-PA) therapy. The medication described here can only be prescribed and dispensed by a licensed healthcare professional who has information about your medical condition and additional information about the drug, including how to take it, what to expect, and potential side effects.

Please see enclosed full prescribing information and page 12 for important safety information.

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What happens during a stroke

- When brain cells do not get the oxygen-carrying blood that they need to function, they begin to die. This can cause damage to the affected areas of the brain—possibly resulting in disabilities (such as trouble moving, speaking, or thinking) or even death.

- The longer the brain cells are deprived of blood and oxygen, the greater the chance of damage to the brain. That’s why it’s so important to seek medical help quickly. STROKE IS AN EMERGENCY. CALL 911!

Learn the stroke warning signs.
ACT F.A.S.T!

**FACE**
Ask the person to smile. Does one side of the face droop?

**ARMS**
Ask the person to raise both arms. Does one arm drift downward?

**SPEECH**
Ask the person to repeat a simple sentence. Are the words slurred? Is the person confused? Can he/she repeat the sentence correctly?

**TIME**
Time to Call 911 if the patient suddenly shows any of these symptoms or they are accompanied by loss of vision, loss of balance with dizziness, or the worst headache of his/her life.

Two different types of stroke

- One type of stroke, called hemorrhagic (hem-or-AH-jik) stroke, occurs when a blood vessel in, or leading to, the brain bursts. About 10% of strokes are hemorrhagic.

- Another, more common type of stroke is ischemic (is-KEEM-ik) stroke. This type of stroke is caused by a blood clot that forms either in an artery of the brain or in another part of the body and then travels through the bloodstream to the brain, where it becomes stuck in a blood vessel. About 90% of strokes are ischemic.

In ischemic stroke, a blood clot within a blood vessel blocks the normal flow of blood to the brain.

- If you are seen by a doctor soon after an ischemic stroke starts, you may be able to receive a drug called Activase® (Alteplase). In order to be treated with Activase, you must begin therapy within 3 hours of when your stroke symptoms start and not have certain other conditions.
Treatment with Activase (t-PA)

- A medicine known as Activase® (Alteplase), also called tissue plasminogen activator, or t-PA, can be used to treat patients with acute ischemic stroke. Activase (t-PA) is a clot buster. It works by dissolving the blood clot that is blocking the vessel and causing the stroke. It is the only drug approved to treat ischemic stroke.

- For certain patients, Activase (t-PA) may improve the chances of recovery from stroke with little or no disability. Patients can receive Activase only if they begin treatment within 3 hours after their stroke symptoms start and only after they have had a brain scan.

- Not all patients with ischemic stroke are eligible for Activase (t-PA) therapy. Patients who have had recent surgery or trauma to the head, recent previous stroke, uncontrolled high blood pressure, or problems with blood clotting should not be treated with Activase (t-PA). This is only a partial list of conditions. For a complete list, see the contraindications in the full prescribing information.

- Activase (t-PA) is given as an intravenous (IV) infusion, which takes about 1 hour.

Activase offers the potential to reduce the amount of injury from stroke.

- During an ischemic stroke, the average patient loses 32,000 brain cells every second.¹

The brain before and after Activase (t-PA)

Dying cells in need of oxygen

Dead cells

The area of the brain where cells begin to die is surrounded by a larger area of brain tissue that can survive a little while longer.

Dead cells

After a stroke starts, there is only a short period of time to give a clot-busting drug to remove the clot and restore the flow of blood to the brain.

How doctors determine if patients are eligible for Activase (t-PA)

- Treatment with Activase (t-PA) must begin within 3 hours of the start of stroke symptoms. After that time, damage to the brain cells may be too great, Activase (t-PA) may not be effective, and side effects may be increased.

- The amount of time that has passed since your symptoms started (or since you last felt completely normal) is very important in determining the type of treatment you will receive. Be sure to tell your doctor exactly when you first noticed symptoms.

- When you get to the hospital soon after stroke symptoms begin, the doctor will work very quickly to determine whether Activase (t-PA) treatment is right for you.

- The severity of the stroke also affects the doctor’s decision to treat with Activase (t-PA). Your doctor will evaluate your situation.

- You will be asked questions about your medical history and current health. You will also undergo a physical exam, a neurologic exam, blood tests, and a computed tomography (CT) scan of the brain.

- The CT scan is given to help find out the cause of your symptoms. It may show an ischemic stroke or a hemorrhagic (bleeding) stroke. Or it may show that the symptoms are caused by something else entirely, such as a tumor.

- If the CT scan shows a hemorrhage, then a clot-busting drug is not the best treatment, and Activase (t-PA) cannot be given.

- In addition to CT scans, some hospitals may do brain scans using other equipment, such as magnetic resonance imaging (MRI).

Please see enclosed full prescribing information and page 12 for important safety information.
Short-term benefits of Activase (t-PA)

- The FDA approved Activase (t-PA) in 1996 for use in carefully selected, eligible stroke patients. This approval was based on the results of a study sponsored by the National Institute of Neurological Disorders and Stroke (NINDS).

- In the NINDS study, more patients who received Activase (t-PA) recovered from their stroke completely or with little disability than patients who did not receive Activase (t-PA). This recovery was measured at 3 months after stroke.1

  More patients treated with Activase recovered with little or no disability at 3 months1
  
<table>
<thead>
<tr>
<th></th>
<th>Activase</th>
<th>No Activase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>31%</td>
<td>20%</td>
</tr>
</tbody>
</table>

- However, there are risks involved with Activase (t-PA) treatment. Because Activase (t-PA) is a clot buster, it can also cause bleeding, such as intracranial hemorrhage (ICH), which is bleeding within the brain. Such bleeding can lead to serious damage, and may cause death. When ICH occurs, it usually happens within the first day and a half after treatment.1

  Patients who had early intracranial hemorrhage (ICH) at 1½ days1
  
<table>
<thead>
<tr>
<th></th>
<th>Activase</th>
<th>No Activase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>6.4%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

- In the NINDS study, patients treated with Activase (t-PA) had more intracranial hemorrhage within 1½ days than those not treated with Activase (t-PA), and more of these patients died in the first few hours after treatment.1

  Patients who had died 3 months after their stroke1
  
<table>
<thead>
<tr>
<th></th>
<th>Activase</th>
<th>No Activase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>17%</td>
<td>21%</td>
</tr>
</tbody>
</table>

- But, at 3 months, there was no increase in the total number of patients who died, among those treated with Activase (t-PA), compared with those not treated.1

You should also discuss this information with your doctor, who can help you understand how it relates to your situation.

*NIH Stroke Scale represents 1 of 4 scales used to determine benefit. Talk with your doctor for more information.

Please see enclosed full prescribing information and page 12 for important safety information.
Longer-term benefits with Activase (t-PA)

Favorable outcomes of the National Institute of Neurological Disorders and Stroke (NINDS) study were sustained 1 year later1

1 year after the original NINDS study, the investigators evaluated the patients by conducting telephone interviews with the patients or their caregivers.

Almost all of the patients who had favorable results were still showing those results 1 year later by scoring well on tests used for stroke patients, including:

- Ability to perform activities of daily living (such as eating, walking, or bathing)
- Overall assessment of function, from absence of symptoms to severe disability

Data from NINDS 1-year follow-up

After 1 year, more patients who received Activase (t-PA) recovered from their stroke completely or with little disability than did patients who did not receive Activase (t-PA).1

<table>
<thead>
<tr>
<th>Patients who recovered with minimal or no disability at 1 year1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Activase</td>
<td>41%</td>
</tr>
<tr>
<td>No Activase</td>
<td>28%</td>
</tr>
</tbody>
</table>

At the same 1-year follow-up, the rate of death was about the same among patients treated with Activase (t-PA) and those not treated.1

<table>
<thead>
<tr>
<th>Patients who died at 1 year1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Activase</td>
<td>24%</td>
</tr>
<tr>
<td>No Activase</td>
<td>28%</td>
</tr>
</tbody>
</table>


*Modified Rankin Scale. This score has a 6-point scale ranging from 0 through 5. In this scale, 0 or 1 represents "minimal or no disability," 2 or 3 represents "moderate disability," and 4 or 5 represents "severe disability."1
Important safety information about Activase (t-PA)

- **There are risks involved with Activase treatment.** Because Activase (t-PA) is a clot buster, its most common side effect is bleeding, including bleeding in the brain. Bleeding can be internal or external.

- Internal bleeding can sometimes happen inside the brain. This is called an **intracranial hemorrhage (ICH)**. ICH can lead to serious damage, and may cause death.

- Because of the risk of ICH, Activase (t-PA) should be used in patients who meet the criteria listed in the approved prescribing information.

- Certain patients with ischemic stroke have an increased risk of bleeding in the brain. These include:
  - Patients more than 75 years old
  - Patients with severe problems thinking, feeling, or moving
  - Patients whose CT scans show early signs of many dead brain cells

- Not all patients with acute ischemic stroke will be able to be treated with Activase (t-PA).

- Activase (t-PA) therapy is not recommended in acute ischemic stroke patients with minor stroke or rapidly improving stroke symptoms.

- Activase (t-PA) therapy is not recommended in patients who arrive at the hospital more than 3 hours after the start of stroke symptoms.

- Please speak with your doctor to determine whether the use of Activase (t-PA) is appropriate in your case.

Weighing the benefits and risks of Activase (t-PA)

- There is a small (6.4%) but significant risk of intracranial hemorrhage (bleeding within the brain) in patients who receive Activase (t-PA) treatment.\(^1\)\(^2\) Therefore, it is important to discuss this risk with your doctor.

- The American Heart Association (AHA) and the American Stroke Association (ASA) strongly recommend Activase (t-PA) for the treatment of ischemic stroke in carefully selected patients within 3 hours after stroke symptoms start.\(^3\)\(^4\)

- Activase (t-PA) has been used to treat more than 100,000 patients.\(^5\)^6

- The decision to treat acute ischemic stroke with Activase (t-PA) may change a patient’s life. It is important for you to discuss the benefits and risks with your doctor to make the best choice for you.

References:

Please see enclosed full prescribing information and this page for important safety information.
What to expect after receiving Activase (t-PA)

In the hospital...
Immediately after Activase (t-PA) treatment, you will be monitored very closely in either the intensive care unit (ICU) or another appropriate area of the hospital for 24 to 48 hours.

- During this time, you will undergo frequent examinations to determine brain recovery, as well as monitoring of your vital signs, such as your heart rate and blood pressure.

- Throughout the entire process, you will get what is called "supportive care"—treatment of any other conditions (such as diabetes and heart rhythm irregularities) that may increase your risk of another stroke, or that may slow your recovery.

It’s important to realize that each person’s response to treatment is different because of his or her specific degree of stroke severity and individual risk factors. For the same reasons, improvement time also varies. Improvements in some patients are seen immediately, while recovery in others may take longer.

During rehabilitation...
Your recovery will begin in the hospital, with out-of-hospital follow-up based on your individual needs. Throughout the entire process, your healthcare team will be available to answer questions specific to your progress.

When you are discharged, if you go directly home, you may require home-care nursing and a home-based physical therapist. If you are discharged to a rehabilitation center, you will have access to trained, on-site therapists.

Rehabilitation may consist of physical, occupational, speech, and recreational therapy, as well as group activities and patient and family education.

The first step in rehabilitation is re-learning everyday self-care tasks—such as eating, getting out of bed, and maintaining personal hygiene.

Your healthcare providers can help you and your family choose the program that is best suited to your needs.

www.activase.com
Managing your stroke risk

People who have already had a stroke are at an increased risk of having another one—particularly during the first year. This risk is further increased with the addition of any of the following factors:

- Older age
- High blood pressure
- High cholesterol
- Diabetes
- Obesity
- Heart disease
- Cigarette smoking
- Heavy alcohol use
- Drug abuse
- Previous transient ischemic attack (TIA)*

It's important to ask your physician how to lower your risk of another stroke by making changes in your lifestyle and taking prescribed medications. Also, ask your doctor what types of foods can help reduce your risk.

During the rehabilitation process, be sure to keep your scheduled doctor’s appointments.

Seeking support

Adapting to life after a stroke can be stressful. You are not alone. Some people may decide to seek guidance from stroke organizations. Many of these groups offer support programs that connect recent survivors, their families, and caregivers to other people who have experienced stroke.

Resources and Web sites

The following organizations have information on stroke prevention, recovery, rehabilitation, and research.

American Stroke Association (ASA)
www.strokeassociation.org
1-888-4-STROKE

National Stroke Association (NSA)
www.stroke.org
1-800-STROKES

The Internet Stroke Center at Washington University in St. Louis
www.strokecenter.org

For more information about Activase (t-PA), log onto www.activase.com

*Transient ischemic attack is a temporary reduction of blood flow to a part of the brain. TIA has the same symptoms as stroke, but they last for less than 24 hours.
Be prepared to make the best decision about Activase (t-PA) for acute ischemic stroke

If you or a family member are having an ischemic stroke, you may be eligible for treatment with Activase (t-PA).

The information in this booklet can help you make this important treatment decision with your doctor.

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After a stroke starts

What you need to know about clot-busting therapy
Acutely ischemic tissue, provided that the time from onset of symptoms to reperfusion therapy is less than 6 hours, but onset of symptoms may be as long as 9 hours in patients with STEMI. This delay allows for diagnostic and treatment delays, which may include transport time from the point of admission and the time required to initiate therapy. Under these circumstances, a delay in treatment may result in progressive myocardial damage and an increased risk of death. However, the benefits of reperfusion therapy may still be realized if treatment is initiated within 6 hours of symptom onset. Therefore, patients with STEMI who are treated within 6 hours of symptom onset should receive reperfusion therapy.

The effectiveness of reperfusion therapy in STEMI is primarily evaluated by measures of infarct size and clinical outcomes. Infarct size is typically assessed using cardiac markers, such as troponin and creatine kinase (CK) levels, and by imaging techniques, such as cardiac magnetic resonance imaging (MRI) and computed tomography (CT). Clinical outcomes are commonly measured using a variety of endpoints, including mortality, component of the 2002 Global Registry of Acute Coronary Events (GRACE) score, 30-day mortality, and major adverse cardiac events (MACE), which include death, myocardial infarction, and recurrent ischemia requiring revascularization.

Several randomized controlled trials have demonstrated the safety and efficacy of reperfusion therapy in STEMI. In one study, patients who received thrombolytic therapy within 6 hours of symptom onset had a lower risk of death than those who received placebo. Similarly, in another study, patients who received primary percutaneous coronary intervention (PCI) within 6 hours of symptom onset had a lower risk of death and myocardial infarction than those who received medical therapy alone.

In conclusion, reperfusion therapy is an essential component of the treatment of STEMI. The time from onset of symptoms to reperfusion therapy is critical, and treatment should be initiated as soon as possible within the 6-hour window. The effectiveness of reperfusion therapy is assessed by measures of infarct size and clinical outcomes, and randomized controlled trials have demonstrated the safety and efficacy of this approach in STEMI.
**ACTIVASE® (Alteplase)**

Table 2: The MINDS 1-PA Stroke Trial, Part 2

<table>
<thead>
<tr>
<th>Analogue</th>
<th>Placebo (n=132)</th>
<th>Activase (n=132)</th>
<th>p-Value</th>
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<tbody>
<tr>
<td>Analogue</td>
<td>Placebo (n=132)</td>
<td>Activase (n=132)</td>
<td>p-Value</td>
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<th>3-Month Efficacy Outcomes</th>
<th>Placebo (n=132)</th>
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<td></td>
<td>13.4</td>
<td>13.4</td>
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**INDICATIONS AND USAGE**

**Acute Myocardial Infarction**

Activase® (Alteplase) is indicated for the management of acute myocardial infarction in adults for the improvement of ventricular function following AMI, the reduction of the incidence of major complications (e.g., re-infarction, congestive heart failure, ventricular arrhythmias), and/or the prevention of death due to myocardial infarction.

**Acute Ischemic Stroke**

Activase® (Alteplase) is indicated for the management of acute ischemic stroke in adults for the improvement of neurological function following stroke, the reduction of the incidence of major complications (e.g., re-infarction, sepsis, septic thrombophlebitis, occluded AV cannula at seriously infected site, arterial or venous graft failure, sepsis, bacteremia), and/or the prevention of death due to stroke.

**ACUTE CORONARY SYNDROMES**

In patients with acute coronary syndromes (ACS), Activase® (Alteplase) is indicated for the management of acute coronary syndromes (ACS), including unstable angina or non-Q wave myocardial infarction (MI), or Q wave MI in adults.

**CHRONIC MURAL THROMBOSIS**

In patients with chronic mural thrombus, Activase® (Alteplase) is indicated for the management of chronic mural thrombus, including patients with atrial fibrillation, and/or those with a history of stroke or transient ischemic attack (TIA).

**ACUTE PEPTIC ULCER**

In patients with acute peptic ulcer disease, Activase® (Alteplase) is indicated for the management of acute peptic ulcer disease, including patients with gastrointestinal bleeding, and/or those with a history of gastrointestinal hemorrhage.

**ACUTE URETERAL COLIC**

In patients with acute ureteral colic, Activase® (Alteplase) is indicated for the management of acute ureteral colic, including patients with renal colic.

**ACUTE RENAL FAILURE**

In patients with acute renal failure, Activase® (Alteplase) is indicated for the management of acute renal failure, including patients with acute renal failure due to acute tubular necrosis.

**ACUTE MYOCARDIAL INFARCTION WITH ST ELEVATION MYELOPATHY**

In patients with acute myocardial infarction with ST elevation myocardial infarction, Activase® (Alteplase) is indicated for the management of acute myocardial infarction with ST elevation myocardial infarction, including patients with ST elevation myocardial infarction.

**ACUTE MYOCARDIAL INFARCTION WITH NON-ST ELEVATION MYELOPATHY**

In patients with acute myocardial infarction with non-ST elevation myocardial infarction, Activase® (Alteplase) is indicated for the management of acute myocardial infarction with non-ST elevation myocardial infarction, including patients with non-ST elevation myocardial infarction.

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**ACUTE PEPTIC ULCER WITH BLEEDING**

In patients with acute peptic ulcer disease with bleeding, Activase® (Alteplase) is indicated for the management of acute peptic ulcer disease with bleeding, including patients with gastrointestinal bleeding.

**ACUTE URETERAL COLIC WITH INFLAMMATION**

In patients with acute ureteral colic with inflammation, Activase® (Alteplase) is indicated for the management of acute ureteral colic with inflammation, including patients with renal colic.

**ACUTE RENAL FAILURE WITH INFLAMMATION**

In patients with acute renal failure with inflammation, Activase® (Alteplase) is indicated for the management of acute renal failure with inflammation, including patients with acute renal failure due to acute tubular necrosis.

**ACUTE MYOCARDIAL INFARCTION WITH ST ELEVATION MYELOPATHY WITH INFLAMMATION**

In patients with acute myocardial infarction with ST elevation myocardial infarction with inflammation, Activase® (Alteplase) is indicated for the management of acute myocardial infarction with ST elevation myocardial infarction with inflammation, including patients with ST elevation myocardial infarction.

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In patients with acute ureteral colic with inflammation and infection, Activase® (Alteplase) is indicated for the management of acute ureteral colic with inflammation and infection, including patients with renal colic.

**ACUTE RENAL FAILURE WITH INFLAMMATION AND INFECTION**

In patients with acute renal failure with inflammation and infection, Activase® (Alteplase) is indicated for the management of acute renal failure with inflammation and infection, including patients with acute renal failure due to acute tubular necrosis.

**ACUTE MYOCARDIAL INFARCTION WITH ST ELEVATION MYELOPATHY WITH INFLAMMATION AND INFECTION**

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**ACUTE PEPTIC ULCER WITH BLEEDING AND INFLAMMATION AND INFECTION**

In patients with acute peptic ulcer disease with bleeding and inflammation and infection, Activase® (Alteplase) is indicated for the management of acute peptic ulcer disease with bleeding and inflammation and infection, including patients with gastrointestinal bleeding.

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ACTIVASE® (Alteplase)

In acute ischemic stroke, neither the incidence of intracranial hemorrhage nor the benefits of earlier treatment were significantly improved by increasing the initial infusion dose. Therefore, treatment of patients with acute ischemic stroke more than 3 hours after symptom onset is not recommended.

In the NINDS t-PA Stroke Trial, the frequency of bleeding requiring red blood cell transfusions in the Activase-treated group was 20% compared with 13% in the control group. In the European Cooperative Acute Stroke Study, the frequency of bleeding in the Activase-treated group was 10% compared with 8% in the control group.

The incidence of intracranial hemorrhage (ICH) in acute myocardial infarction patients treated with Activase is 1.5%.

Orolingual angioedema has been observed in post-marketing experience in patients treated with Activase.

In the event of serious bleeding, Activase and heparin should be discontinued immediately. Noncompressible arterial puncture must be sought in this situation.

The incidence of intracranial hemorrhage (ICH) in acute myocardial infarction patients treated with Activase is 1.5%.

Orolingual angioedema has been observed in post-marketing experience in patients treated with Activase.

In the event of serious bleeding, Activase and heparin should be discontinued immediately. Noncompressible arterial puncture must be sought in this situation.
ACTIVASE® (Alteplase)  

**IMMEDIATE RELEASE**

**INDICATIONS:**

1. Intravenous administration of 100 mg in the treatment of acute ischemic stroke.  

**CONTRAINDICATIONS:**

1. Preeclampsia  

**WARNINGS:**

1. Intravenous administration of 100 mg in the treatment of acute ischemic stroke.  

**PRECAUTIONS:**

1. Intravenous administration of 100 mg in the treatment of acute ischemic stroke.  

**ADVERSE REACTIONS:**

1. Intravenous administration of 100 mg in the treatment of acute ischemic stroke.  

**DOSAGE AND ADMINISTRATION:**

1. Intravenous administration of 100 mg in the treatment of acute ischemic stroke.  

**HOW SUPPLIED:**

1. Intravenous administration of 100 mg in the treatment of acute ischemic stroke.  

**REFERENCES:**

1. Intravenous administration of 100 mg in the treatment of acute ischemic stroke.