

### Risk/Benefit Information t-PA

1. In a large study conducted by the National Institute of Neurological Diseases and Stroke (NINDS Stroke Study), selected patients with stroke were treated with rt-PA or placebo (an inactive substance) by random (chance) assignment within 3 hours of symptom onset. **This study showed at least 11 out of 100 patients treated with rt-PA as compared to those receiving placebo had minimal or no disability at 3 months after treatment.**

Within the first 36 hours after stroke onset, **6.4% of patients who received rt-PA as compared to 0.6% of patients who received placebo had bleeding in the brain that resulted in worsening of the stroke. There was no significant difference in the number of patients who died treated with rt-PA (17%) and those treated with placebo (21%).** Patients treated with rt-PA who had a very severe stroke or were of advanced age (>77 years old) tended to have more symptomatic bleeding.

Based on the results of the NINDS study, rt-PA has been approved by the FDA for use for selected stroke patients provided it can be given within 4 hours of stroke onset.

2. In addition to obtaining informed consent from your patient, patients receiving t-PA must be admitted to an intensive care unit for at least 24 hours to be observed for any complications related to rt-PA treatment and undergo a CT scan of the head prior to treatment to determine the presence of bleeding within the brain. Follow-up CT scans may be done to determine bleeding complications within the brain.
3. t-PA dissolves blood clots, regardless of their location in the body. Therefore, its most frequent side effect is bleeding. Minor bruising and bleeding of blood vessel sites that have been punctured is not uncommon and is generally easily controlled. Occasionally bleeding may be severe enough to require blood transfusions. There is also a risk of serious internal bleeding, which is more difficult to control. Bleeding in the brain may cause stroke. With t-PA treatment, there is a risk of bleeding in the brain (stroke), which can lead to permanent disability or death. Even without treatment with t-PA, stroke patients have a risk of bleeding in the brain.

Other side effects that may occur with rt-PA are nausea and/or vomiting, low blood pressure, and fever. These have been reported in patients receiving rt-PA for treatment of a heart attack and may have been related to the heart attack rather than the medication.

4. Angioedema (with swelling of the airway) or other serious allergic reactions may also occur.
5. Pregnant patients should not receive rt-PA, as there is no known information regarding potential harm to the fetus they are carrying.