


Alemtuzumab (Lemtrada)

Patient Information

<p>USED FOR</p>	<ul style="list-style-type: none"> Relapsing remitting multiple sclerosis (MS) Alemtuzumab will not cure MS. It may reduce flare-ups and slow the worsening of symptoms. Because of its risks, Alemtuzumab is generally used in people who have tried 2 or more MS medicines that have not worked well enough. 	
<p>HOW IT WORKS</p>	<ul style="list-style-type: none"> Alemtuzumab modifies the immune system by eliminating immune cells such as T and B cells from the body. It is hoped that this reduces injury to nerve cells. 	
<p>HOW IT IS GIVEN</p> 	<ul style="list-style-type: none"> Alemtuzumab is mixed in a 100ml fluid bag and is given by infusion through a needle placed in a vein in your arm (intravenous infusion). You will be required to go to an infusion center for the administration of the drug. 	
<p>DOSE</p>	<ul style="list-style-type: none"> Alemtuzumab is typically given in a total of 2 treatment courses <ul style="list-style-type: none"> First treatment: 12mg once a day for 5 consecutive days (60mg total) Second treatment: 12mg once a day for 3 days (36mg) given 12 months after the first treatment 	
<p>UCSF INFUSION CENTERS</p>	<ul style="list-style-type: none"> BEFORE scheduling your appointment with an infusion center, you must get authorization from your insurance After you have scheduled your appointment at the infusion center, arrange for at least 2 weeks of time off of work, contact your MS doctor to set up lab monitoring and specific instructions to prepare for your infusion. 	
	<ul style="list-style-type: none"> Ron Conway Family Gateway Medical Building <p>1825 Fourth St., Third Floor San Francisco, CA 94158 Phone: (415) 353-7155 Hours: Monday to Friday 8 a.m. - 8 p.m. Saturday 9 a.m. - 5 p.m</p>	<ul style="list-style-type: none"> Ida Friend Infusion Center <p>1600 Divisadero St., Fifth Floor San Francisco, CA 94143 Phone: (415) 353-7155 Hours: Monday to Friday 8 a.m. - 6 p.m. Saturday 9 a.m. - 4 p.m.</p>
<p>INFUSION SIDE EFFECTS AND REACTIONS</p>	<ul style="list-style-type: none"> You will be monitored closely and treated with medications if any hypersensitivity reactions occur: hives, dizziness, fever, rash, chills, itching, nausea, flushing, low blood pressure, shortness of breath, and chest pain 	

	<ul style="list-style-type: none"> • Serious infusion reactions can occur and may cause death. It may happen while you receive, or up to 24 hours or longer after your infusion is completed. The infusion center will have trained staff with equipment and medications to manage infusion reactions during and after the infusion. • You will be observed for 2 hours after the infusion is complete to make sure there are not any side effects or hypersensitivity reactions. Plan to be at the infusion center for at least 6 hours or longer. • If a serious infusion reaction happens, your infusion will be stopped and your doctor will be notified.
<p>BEFORE THE INFUSION APPOINTMENT</p>	<ul style="list-style-type: none"> • If any 'live' or 'live attenuated' vaccines are required, these should be given at least 6 weeks prior to your infusion. • Within 30 days of the infusion: you will need to have a complete blood count, lymphocyte subsets (CD4+ count), chemistries, liver function tests, hepatitis B and C tests, HIV test, urinalysis with microbiology, tuberculosis test, and thyroid function tests, and an evaluation of your skin by a dermatologist. If you are a woman, you will need HPV screening. • Pick up medications prescribed at the pharmacy in preparation for the infusion: cetirizine (Zyrtec), acetaminophen (Tylenol), famotidine (Pepcid), Valacyclovir (Valtrex) • 3 days before the first infusion: start taking cetirizine 10 mg by mouth daily, famotidine 20 mg daily, and continue for 30 days to reduce the chance of serious reactions. • On each day of the infusion: eat breakfast and hydrate well (8-10 glasses of water) before your infusion. • If you are a woman and able to become pregnant, you should use birth control during the infusion and for 4 months after your treatment course
<p>AT THE INFUSION CENTER</p>	<ul style="list-style-type: none"> • 1 hour prior to your infusion appointment, you will need a urine pregnancy test at the infusion center lab if you are a woman and able to become pregnant. You will not be able to start the infusion if you are pregnant. • On the first day of the Alemtuzumab infusion: start taking Valacyclovir 500mg by mouth in the morning then once in the evening (twice daily) • You will be given medication before or after the infusion to reduce your chances of serious infusion reactions or to treat them after they happen. • For the first 3 days of each treatment course, 1 hour before each infusion: you will also be infused with a steroid, Methylprednisolone (Solu-medrol) 1000mg over 30min -1 hour • Just prior to every infusion: you will receive diphenhydramine (Benadryl) 25mg IV and acetaminophen 650mg by mouth. • After pre-medications: Alemtuzumab will be infused at slow rate that will last for

	4 hours or more	
AFTER THE INFUSION	<ul style="list-style-type: none"> • You are likely to have a rash, a headache, nausea, and fatigue after the infusion. You should continue to take cetirizine and as needed diphenhydramine for the rash, acetaminophen for any pain, and famotidine for any stomach issues for 30 days. • To prevent herpes infection, continue Valacyclovir until you are instructed by your MS doctor to stop taking. You will most likely need to take Valacyclovir for 2 months or longer. • Serious side effects may happen while you receive Alemtuzumab and for 4 years after you stop. For the next 4 years after the last infusion you will need regular blood work and screening tests to help your MS doctor find any problems early and will increase your chances of getting better. <i>*All blood work after the infusion will be free of charge via a program at LabCorps or Quest, or EMSI home phlebotomy service.</i> <ul style="list-style-type: none"> ○ Every month: complete blood count, urinalysis, creatinine, lymphocyte subsets (CD4+ count). ○ Every 3 months: thyroid function tests ○ Once a year: skin exam and HPV screening (if you are a woman) • To prevent any infection: avoid sick contacts, wash your hands, do not eat raw or unpasteurized dairy products that can increase your chance of infection with listeria, and avoid swimming in lakes and streams 	
COMMON SIDE EFFECTS	<ul style="list-style-type: none"> • rash • headache • thyroid problems • fever • swelling of your nose and throat (nasopharyngitis) • nausea • urinary tract infection • sinus infection • upper respiratory tract infection • herpes viral infection • feeling tired • trouble sleeping • hives • itching 	<ul style="list-style-type: none"> • fungal infection • joint pain • pain in your arms or legs • back pain • diarrhea • mouth pain or sore throat • tingling sensation • dizziness • stomach pain • sudden redness in face, neck, or chest • vomiting
RARE, BUT SERIOUS SIDE EFFECTS	<ul style="list-style-type: none"> • Serious autoimmune problems: <ul style="list-style-type: none"> ○ Immune thrombocytopenic purpura (ITP): Reduced number of platelets and severe bleeding that, if not treated, may cause life-threatening problems. <ul style="list-style-type: none"> ▪ Call your MS doctor right away if you have any of the following symptoms: easy bruising, bleeding from a cut that is hard to 	

stop, heavier menstrual periods than normal, bleeding from your gums or nose that is new or takes longer than usual to stop, small, scattered spots on your skin that are red, pink, or purple (petechial rash). See below examples of petechial rash:



- **Serious kidney problems:** anti-glomerular basement membrane disease. If not treated, it can lead to severe kidney damage, kidney failure that needs dialysis, a kidney transplant, or death.
 - Call your MS doctor right away if you have any of the following symptoms: blood in the urine (red or tea-colored urine), swelling in your legs or feet, coughing up blood
- **Increased chance of certain cancers:** thyroid cancer, skin cancer (melanoma), and blood cancers called lymphoproliferative disorders and lymphoma.
 - Call your healthcare provider if you have the following symptoms that may be a sign of thyroid cancer: new lump, swelling in your neck, pain in the front of your neck, hoarseness or other voice changes that do not go away, trouble swallowing or breathing or cough that is not caused by a cold
- Other serious side effects
 - Thyroid problems: overactive (hyperthyroid) and underactive (hypothyroid)
 - Low blood counts (CD4+ lymphocytes) which can increase your risk of infection
 - Serious infections: herpes viral infection, human papilloma virus (HPV), tuberculosis, fungal infections, bacterial infections (listeria)
 - Swelling of lung tissue (pneumonitis)

DRUG INTERACTIONS

- Alemtuzumab taken before or after other medicines that weaken the immune system could increase your risk of getting infections.

MORE INFORMATION

- Websites: www.lemtrada.com, www.nationalmssociety.org
- Clinical Trials:
 1. Cohen JA, et al. Lancet. 2012;380(9856):1819-28.
 2. Coles AJ, et al. Lancet. 2012;380(9856):1829-39.