What you should know about alemtuzumab

Call your neurologist right away to report these symptoms no matter if they are new, worsening or returning symptoms. Seek medical attention if you cannot reach your own doctor, and make sure you show them this card.

IMPORTANT SIDE EFFECTS TO WATCH FOR:

Serious infections

Fever, chills, fatigue, swollen glands, shortness of breath, cough, wheezing, chest pain or tightness and coughing up blood.

Rare brain infection called PML (progressive multifocal leukoencephalopathy)
- Progressive weakness or clumsiness of limbs
- Disturbance of vision, speech difficulties or
- Changes in thinking, memory, and orientation leading to confusion and personality changes

Serious side effects occurring shortly after alemtuzumab infusion
(usually within 1–3 days of infusion)

Heart attack
- Chest pain or discomfort, shortness of breath, pain or discomfort in arms, jaw, neck, back or stomach
- Feeling dizzy or lightheaded, nausea, sweating

Stroke and tears in blood vessels supplying the brain
- Sudden onset of drooping of parts of the face, weakness on one side, difficulty with speech
- Sudden severe headache, neck pain

Bleeding in the lungs
- Shortness of breath, chest pain or discomfort, coughing blood

Thrombocytopenia
- Easy bruising and/or bleeding

Delayed side effects (which can occur months to years after infusion)

Thyroid disorders
- Hyperthyroidism: excessive sweating, unexplained weight loss, eye swelling, nervousness, fast heartbeat
- Hypothyroidism: feeling cold, unexplained weight gain, worsening tiredness, newly occurring constipation

Immune thrombocytopenic purpura (ITP)
- Small scattered spots on your skin that are red, pink or purple, easy bruising, bleeding from a cut that is harder to stop than usual, heavier, longer or more frequent menstrual periods than normal
- Bleeding from your gums or nose that is new or takes longer than usual to stop, coughing up blood

Kidney problems including anti-Glomerular Basement Membrane disease (anti-GBM disease)
- Blood in the urine which may be red or tea-coloured, swelling in your legs or feet, coughing up blood

Autoimmune hepatitis
- Unexplained nausea, vomiting, fatigue, abdominal pain, loss of appetite, abdominal swelling
- Yellow skin and eyes and/or dark urine, bleeding or bruising more easily than normal

Haemophagocytic lymphohistiocytosis (HLH)
- Unexplained high fever, swollen glands, yellow skin, skin rash

Acquired haemophilia A
- Bleeding from a cut that takes longer than usual to stop
- Spontaneous bruising, nose bleeds, painful or swollen joints

Thrombotic thrombocytopenic purpura (TTP)
- Bruising under the skin, or in the mouth, that may appear as red pinpoint dots, with or without unexplained extreme tiredness, fever, confusion, speech changes, yellowing of the skin or eyes (jaundice), low amount of urine, dark coloured urine

Adult onset still's disease (AOSD)
- Fever >39°C or 102.2°F lasting more than 1 week, pain, stiffness with or without swelling in multiple joints and/or a skin rash

Autoimmune encephalitis (AIE)
- Behavioural and/or psychiatric changes, short term memory loss or seizures. The symptoms may resemble an MS relapse

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It's very important that you continue to attend your monthly tests for at least 48 months (4 years) after your last infusion (even if you are feeling well).

Delayed side effects may occur beyond 48 months. Therefore you must continue to look out for the signs, even after your monthly tests are no longer required.

Early detection and diagnosis may give you the best opportunity for improvement

You must also continue to watch for signs and symptoms

Do this for at least 48 months after your last course of treatment with alemtuzumab

	Name	Phone number	Email
Neurologist			
General Practitioner			
MS Nurse			

My neurologist prescribing alemtuzumab can be contacted via phone or email using the details below.
Other doctors or healthcare professionals involved in my care may also be listed.

If any medical evaluations are undertaken, please provide copies of all medical records, including any treatments and/or test results, to the doctor(s) and nurse(s) listed below.

Patient's name:.....

Patient's signature:.....

Date of last alemtuzumab infusion:.....

PATIENT ALERT CARD – IE

Please carry this card with you at all times and show it to all emergency and healthcare providers involved in your care to inform them about your treatment with LEMTRADA® ▼ (alemtuzumab).

I have been treated with alemtuzumab, a treatment for multiple sclerosis (MS), which affects the immune system.
I am participating in a special monitoring programme which continues for at least 48 months after my last treatment.

Alemtuzumab treatment may increase the risk of:

- Serious infections
- Serious side effects that usually occur within 1 to 3 days of infusion: heart attack, stroke, tears in blood vessels supplying the brain, bleeding in the lung, and thrombocytopenia
- Delayed side effects: thyroid disorders, a bleeding disorder caused by a low level of blood platelets, called immune thrombocytopenic purpura (ITP), kidney problems, liver inflammation (autoimmune hepatitis), excessive activation of white blood cells associated with inflammation (haemophagocytic lymphohistiocytosis (HLH)), a bleeding disorder caused by antibodies that work against factor VIII (a protein needed for normal clotting of blood), called acquired haemophilia A, Thrombotic thrombocytopenic purpura (TTP) (blood clotting problem where blood clots form in blood vessels and can happen all over the body), adult onset still's disease (AOSD) (a rare inflammatory condition that requires urgent evaluation and treatment), and autoimmune encephalitis (AIE) (a rare disorder of the immune system).

Doctors: See alemtuzumab Summary of Product Characteristics (SmPC) for more information.

▼ This medicinal product is subject to additional monitoring. This will allow for quick identification of new safety information. You can help by reporting any side effects you may get.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects directly to HPRA Pharmcovigilance, website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Sanofi: Tel: 01 403 5600. Email: IEPharmacovigilance@sanofi.com