swissmedic

Summary report on authorisation dated 20 April 2026

Imaavy® (active substance: nipocalimab)

Authorisation in Switzerland: 18 December 2025

Concentrate for solution for infusion for the treatment of patients aged 12 years of age and older with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive, as an add-on to standard therapy

About the medicinal product

Imaavy contains the active substance nipocalimab and is a monoclonal antibody.

Imaavy is used as an add-on to standard therapy for the treatment of adolescents aged 12 years of age and older and adults with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Myasthenia gravis is a chronic, neuromuscular autoimmune disease that leads to muscle weakness. "Generalised" means that muscles throughout the body are affected.

The disease is often episodic and shows typical fluctuations during the day with symptoms worsening as the day progresses or on exertion.It can severely disrupt everyday life.

In gMG, the immune system produces antibodies against the body's structures that are important for signal transmission between nerves and muscles. Such structures include AChR and MuSK. As a result, these antibodies interfere with the transmission of signals from the nerves to the muscles.

Imaavy was authorised as part of the joint initiative of the Access Consortium.This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.
The authorisation application for Imaavy was submitted to the drug regulatory authorities in Canada and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the authorisation independently.
Swissmedic considered the assessments by the foreign reference authorities in its decision on the authorisation.

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch).

Since gMG is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Mode of action

In gMG, the immune system mistakenly attacks structures that are important for the communication between nerves and muscles, including AChR and MuSK.

The immune system forms immunoglobulin class G (IgG) antibodies that disrupt the signal transmission from the nerves to the muscles, leading to muscle weakness.

Imaavy binds to the neonatal Fc receptor (FcRn), which is normally responsible for ensuring that IgG antibodies are able to remain and work in the body for longer. By blocking FcRn, IgGs are degraded at a faster rate, thereby lowering the levels of the disease-causing IgG antibodies against AChR and MuSK. This reduces the disease-triggering effect of the antibodies and improves the signal transmission between nerves and muscles, thereby helping to reduce the muscle weakness.

Administration

Imaavy is a prescription-only medicine.

Imaavy is administered intravenously and is available as a vial containing 300 mg of nipocalimab in 1.62 ml or a vial containing 1200 mg of nipocalimab in 6.5 ml.

The recommended initial dose is 30 mg per kilogram of body weightadministered intravenously over approximately 30 minutes. This is followed by maintenance therapy with a single dose of 15 mg per kilogram of body weight every two weeks administered intravenously over approximately 15 minutes.

There are certain scenarios in which treatment with Imaavy should be discontinued (e.g. if no clinical improvement has been achieved after 24 weeks of treatment, or if the symptoms have even deteriorated during treatment).

The treatment with Imaavy does not replace another treatment, but is used in addition to the existing standard treatment for gMG.

Efficacy

The efficacy of Imaavy was investigated in several clinical studies, primarily the Phase 3 study (MOM-M281-011), which was pivotal for the authorisation in adult patients.

In this trial, 196 adults were treated for a period of 24 weeks. All participants continued to receive their existing standard treatment. They additionally received either Imaavy (98 subjects) or a placebo (dummy drug, 98 subjects).

The effect was measured with two recognised clinical assessment scales: the MG-ADL score (Myasthenia Gravis – Activities of Daily Living), a questionnaire that assess the effects of the symptoms of gMG on the activities of daily living, and the QMG score (Quantitative Myasthenia Gravis scale), which provides an objective quantitative estimation of disease severity based on the examination of certain muscle groups.

In the patients who received Imaavy, both the MG-ADL and the QMG scores improved to a greater extent than in the placebo recipients. Specifically, the MG-ADL score in the group of patients treated with Imaavy fell by an average of 1.45 points more than in the placebo group, while the QMG score

fell by 2.81 points more than in the placebo group. These effects were statistically significant, meaning that both the adverse impact on daily life and the strength in various muscle groups improved to a greater extent in the subjects receiving add-on treatment with Imaavy than in those who received the placebo.

Efficacy in adolescents aged from 12 to under 18 years was investigated in the open-label Phase 2/3 study (MYG2001). Eight adolescents, all AChR antibody positive, received Imaavy for 24 weeks in addition to their standard therapy. The treatment produced improvements similar to those in adults.

These results show that Imaavy – in addition to the existing standard treatment – can effectively reduce the symptoms of gMG.

Precautions, undesirable effects, & risks

Imaavy must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most commonly reported side effects (affecting more than 10% of patients) include elevated blood lipid levels (total cholesterol and LDL cholesterol), muscle spasms, swelling of the arms or legs (peripheral oedema), urinary tract infections and a reduction in the blood IgG level.

Since Imaavy can affect the immune response, the risk of infections may be increased. The treating doctors must also monitor the patients for signs of deteriorating muscle weakness, since the symptoms of gMG can worsen during treatment.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

gMG is an autoimmune disease that causes muscle weakness and significantly impairs the daily lives of sufferers. Despite existing treatment options, there is still an unmet need for effective treatments, particularly for patients who do not respond well to standard treatments. Imaavy offers an additional therapeutic option for this patient group by lowering the concentration of disease-causing antibodies. Clinical trials have shown that, when used as an add-on to existing treatments, Imaavy can produce a clinically significant improvement in muscle weakness and functional capacity in daily life in certain patients. Although some risks are involved, including elevated blood lipid levels and the possibility of infections, the benefits in terms of improving the patients' disease symptoms and quality of life outweigh these risks. It should be noted that, since the response to treatment can vary from person to person and uncertainties exist in specific patient groups, Swissmedic has defined criteria for discontinuing the treatment. Taking all the risks and precautions into account, and based on the available data, the benefits of Imaavy outweigh the risks. Swissmedic has therefore authorised the medicinal product Imaavy, containing the active substance nipocalimab, in Switzerland for the treatment of patients 12 years of age and older with gMG, who are AChR or MuSK antibody positive, as an add-on to the individual standard therapy.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Imaavy®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.