swissmedic

Summary report on authorisation dated 7 August 2026

RYSTIGGO® (active substance: rozanolixizumab)

Authorisation in Switzerland: 12 February 2025

Solution for injection for the treatment of generalised myasthenia gravis (gMG) in adult patients with certain antibodies implicated in the development of the disease.

About the medicinal product

RYSTIGGO contain the active substance rozanolixizumab, a genetically engineered antibody.

The medicinal product is used to treat generalised myasthenia gravis (gMG). gMG is a rare, chronic autoimmune disorder in which the body's immune system erroneously attacks structures that are important for signal transmission between nerves and muscles. The result is muscle weakness that worsens with muscle effort and rapid muscle fatigue, for example when walking, working, speaking, swallowing or breathing.

RYSTIGGO is used in adult patients who have tested positive for certain antibodies that attack endogenous structures and are implicated in the development of the disease (what are known as anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) autoantibodies). It is used as an add-on to existing standard gMG therapy in cases where the disease is not adequately controlled.

Since gMG is a rare and potentially life-threatening or chronically debilitating disease, the medicinal product RYSTIGGO has been authorised as an orphan drug. The term "orphan drug" refers to medicinal products used to treat patients with rare diseases.

RYSTIGGO was assessed under the Access Consortium.

The Access Consortium is a joint work sharing initiative 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 Switzerland (Swissmedic). It coordinates the joint assessment of medicinal products that have been submitted for authorisation in at least two of the five countries.

The authorisation application for RYSTIGGO was submitted in parallel to the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC) and Switzerland. Each authority assessed part of the application. They then exchanged and discussed the assessments. At the end of the process, each authority makes its own decision on authorisation.

Further information on the Access joint initiative can be found on the Swissmedic website: Access Consortium (swissmedic.ch).

Mode of action

RYSTIGGO speeds up the excretion of all type G antibodies (known as immunglobulin G (IgG)) produced in the body. These account for approximately 75-80% of all the antibodies produced in the body.

As a result, the IgG autoantibodies implicated in gMG are broken down faster. When this happens, the disrupted communication between nerves and muscles may improve and the symptoms may subside.

Administration

RYSTIGGO is a prescription-only medicine.

RYSTIGGO is administered by means of an infusion pump as a solution for subcutaneous (under the skin) injection. One (1) ml of solution for injection contains 140 mg of rozanolixizumab.

The dosage is based on the patient's weight. Normally, one dose is administered once a week for six weeks (treatment cycle).

Additional treatment cycles may be undertaken, depending on the course of the disease. However, a minimum period must be maintained between two cycles.

Treatment is initiated and supervised by a doctor experienced in neuromuscular disease.

Efficacy

The efficacy of RYSTIGGO has been investigated in clinical studies involving adult patients with gMG.

Around 200 patients took part in the main study (MG0003). They received either RYSTIGGO or a dummy medicinal product (placebo) for six weeks, after which they were followed up in an eight-week observation period.

In particular, the study investigated the extent to which the restrictions to everyday life typically associated with gMG changed.

Some patients who were treated with RYSTIGGO experienced an improvement in the symptoms of their disease compared to placebo.

Many patients showed an improvement in their symptoms during the first weeks. Overall, more people who received treatment achieved a perceptible improvement than with placebo.

However, since not every patient responds to treatment, constant monitoring by a doctor is necessary during treatment so that it can be stopped after an appropriate period if it proves ineffective.

Repeated cycles produced an observable sustained effect in some patients.

Precautions, undesirable effects, & risks

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

Since RYSTIGGO reduces the levels of certain antibodies in the body, the risk of infections may be increased. Treatment may have to be

interrupted in the event of existing or new infections.

Vaccinations should be scheduled appropriately because certain vaccines are not recommended while treatment is in progress.

The most common undesirable effects (affecting more than one in ten users) are headache, diarrhoea, upper respiratory infections, fever, stomach pain, nausea, injection site reactions and joint pain.

In rare cases, more serious reactions can occur, such as hypersensitivity reactions or certain types of inflammation (e.g. aseptic meningitis).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

RYSTIGGO offers a new treatment option for patients with gMG whose disease is not adequately controlled even though they are taking a standard therapy.

The studies showed that RYSTIGGO can improve some patients' symptoms when used as an add-on to their standard gMG therapy. Among other things, restrictions to everyday life caused by gMG improve. The treatment effect may also persist during repeated treatment cycles.

Taking all the risks and precautions into account, and based on the available data, the benefits of RYSTIGGO outweigh the risks. Swissmedic has therefore authorised the medicinal product RYSTIGGO containing the active substance rozanolixizumab for use in Switzerland as an add-on to standard therapy for generalised myasthenia gravis (gMG) in adult patients who have tested positive for anti-AChR (acetylcholine receptor) or anti-MuSK (muscle-specific tyrosine kinase) antibodies.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals RYSTIGGO®

Information for patients (package leaflet): Information for patients RYSTIGGO®
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.