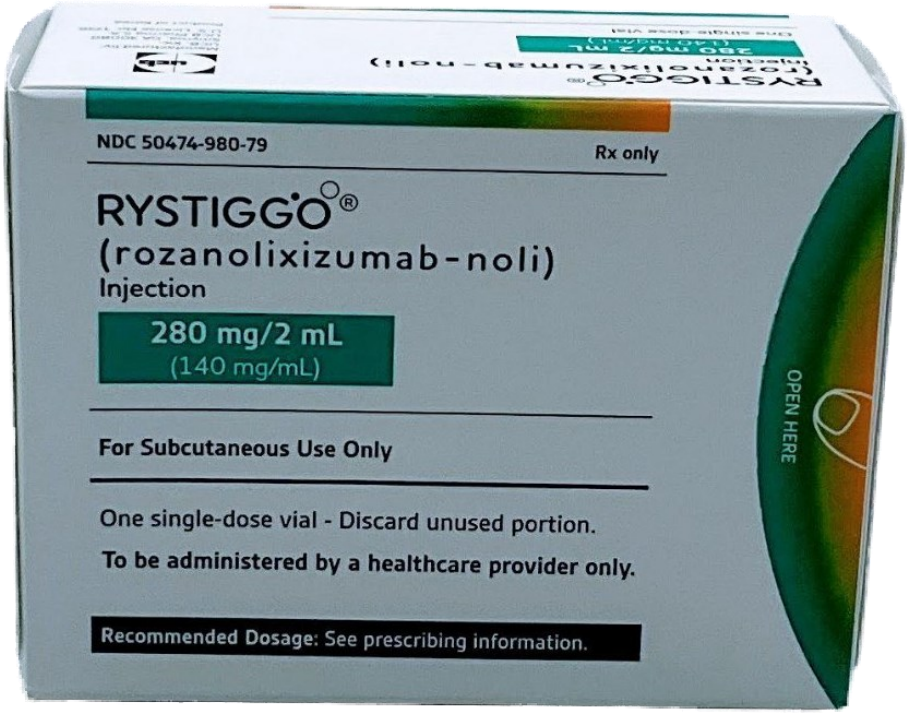
INPHARMD™ **MONOGRAPHS**

Rystiggo®

(Rozanolixizumab-noli)

The latest evidence on drug efficacy & recommendations.



InpharmD™

UPDATED JUNE 2024

OVERVIEW

REGIMEN

Generic Name	Rozanolixizumab-noli
Trade Name	Rystiggo®
Manufacturer	UCB, Inc.
FDA Approval	June 27, 2023
Therapeutic Class	Neonatal FC Receptor Antagonist

Dosage

Weight-based dosing as subcutaneous infusion once weekly for 6 weeks:

<50 kg = 420 mg
50 to <100 kg = 560 mg
≥100 kg = 840 mg

Indications

Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive

PHARMACOLOGY

Rozanolixizumab-noli is a humanized IgG4 monoclonal antibody that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG.

PHARMACODYNAMICS

In patients testing positive for AChR and MuSK autoantibodies who were treated with RYSTIGGO, there was a reduction in total IgG levels relative to baseline. Decreases in AChR autoantibody and MuSK autoantibody levels followed a similar pattern.

PHARMACOKINETICS

Absorption

Peak plasma levels: ~ 2 days.

Distribution

Vd: 6.6 L

Metabolism

Degraded by proteolytic enzymes into small peptides and amino acids

Excretion

CL: 0.89 L/day

CLINICAL DATA OVERVIEW

N= 43 • Bril et al., 2021 • Phase 2a, randomized, double-blind, placebo-controlled, 2-period, multi-center trial (NCT03052751)

POPULATION

Objective: To explore the clinical efficacy and safety of subcutaneous (SC) rozanolixizumab, an anti-neonatal Fc receptor humanized monoclonal antibody, in patients with generalized myasthenia gravis (gMG).

N= 43
Rozanolixizumab (n= 21)
Placebo (n= 22)

METHODS

Inclusion: Aged ≥18 years, moderate to severe gMG, evidence of elevated autoantibodies (anti-acetylcholine receptor [AChR] or anti-muscle-specific kinase [MuSK]) prior to screening

Exclusion: only ocular MG, myasthenic crisis, severe weakness affecting oropharyngeal or respiratory muscles, renal impairment, elevated hepatic enzymes, previous rituximab, immunosuppressants, biologic agents, immunoglobulins, PLEX, and other therapies at designated time points before baseline visit

Intervention: Period 1 (days 1–29): Patients were randomized (1:1) to 3 once-weekly (Q1W) subcutaneous (SC) infusions of rozanolixizumab 7 mg/kg or placebo.

Period 2 (days 29–43): Patients were re-randomized to either rozanolixizumab 7 mg/kg or 4 mg/kg (3 Q1W SC infusions), followed by an observation period (days 44–99).

Follow-up: 100 days

RESULTS

Primary end point: Change from baseline to day 29 in Quantitative Myasthenia Gravis (QMG) score:
Least squares (LS) mean change of QMG was not significantly different for rozanolixizumab vs placebo (−1.8 vs −1.2; difference −0.7; 95% upper confidence limit [UCL] 0.8; p= 0.221)

Secondary end point: Change from baseline to day 29 in MG-Activities of Daily Living (MG-ADL) and MG- Composite (MGC) scores:
LS mean change of MG-ADL was −1.8 vs −0.4, respectively (difference −1.4; 95% UCL −0.4)
LS mean change of MGC was −3.1 vs −1.2, respectively (difference −1.8; 95% UCL 0.4) scores. Efficacy measures continued to improve with rozanolixizumab 7 mg/kg in period 2.

Safety:
Adverse events (AEs) in period 1 (rozanolixizumab vs. placebo): headache (57% vs. 14%); diarrhea (14% vs. 9%); nausea (10% vs 5%); nasopharyngitis (5% vs. 14%); upper respiratory tract infection (10% vs. 5%)

CONCLUSIONS

Authors' conclusions: Whereas change from baseline in QMG was not statistically significant, the data overall suggest rozanolixizumab may provide clinical benefit in patients with gMG and was generally well tolerated.

Comment/Critique:

Aside from the small sample size and lack of comparative group, data on the duration of MG were not collected. A longer duration of treatment seems to be warranted to evaluate the significance of outcomes in this patient population.

Study sponsor: UCB Pharma, the manufacturer of rozanolixizumab.

N = 200 • Bril et al., 2023 • Multi-center, randomized, double-blind, placebo-controlled, adaptive phase 3 study (NCT03971422)

POPULATION

Objective: To study the safety and efficacy of rozanolixizumab in adults with AChR or MuSK autoantibody-positive generalized myasthenia gravis.

N= 200
Rozanolixizumab 7 mg/kg (n= 66)
Rozanolixizumab 10 mg/kg (n= 67)
Placebo (n= 67)

METHODS

Inclusion: Aged ≥18 years, generalized MG (Myasthenia Gravis Foundation of America Class II-Iva disease), presence of AChR or MuSK autoantibodies, at least 35 kg. Permitted medications: cholinesterase inhibitors, oral corticosteroids, azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, tacrolimus

Exclusion: oropharyngeal or respiratory weakness, infection, pregnancy, breastfeeding. Prohibited medications: IV immunoglobulin, plasma exchange, biologic agents, certain immunosuppressants

Intervention: Patients were randomly assigned (1:1:1) to receive SQ infusions of either rozanolixizumab 7 mg/kg, rozanolixizumab 10 mg/kg, or placebo once a week for 6 weeks

Follow-up: 42 days (6 weeks)

RESULTS

Primary end point: Change from baseline to day 43 in MG-ADL score
MG-ADL score was significantly reduced in the rozanolixizumab 7 mg/kg group (LS mean change –3.37 ± 0.49) and in the rozanolixizumab 10 mg/kg group (–3.40 ± 0.49) vs. placebo (–0.78 ± 0.49; for 7 mg/kg, LS mean difference −2.59; 95% confidence interval [CI] −4.09 to −1.25; p< 0.0001; for 10 mg/kg, −2.62; 95% CI −3.99 to −1.16; p< 0·0001).

Secondary end point: Change from baseline to day 43 in MGC and QMG
Both rozanolixizumab groups showed statistically significant improvements vs. placebo for change from baseline to day 43 in MGC and QMG scores (p< 0.001 for all comparisons).

Safety:
Common AEs in rozanolixizumab 7 mg/kg vs. rozanolixizumab 10 mg/kg vs. placebo: headache (45% vs. 38% vs.19%); diarrhea (25% vs. 16% vs. 13%); pyrexia (13% vs. 20% vs. 1%)

CONCLUSIONS

Author's Conclusions:
Rozanolixizumab showed clinically meaningful improvements in patient-reported and investigator-assessed outcomes in patients with generalized myasthenia gravis, for both 7 mg/kg and 10 mg/kg doses. Both doses were generally well tolerated. These findings support the mechanism of action of neonatal Fc receptor inhibition in generalized myasthenia gravis. Rozanolixizumab represents a potential additional treatment option for patients with generalized myasthenia gravis.

Comment/Critique: Although both doses of rozanolixizumab demonstrated comparable efficacy and safety outcomes, this study still lacks a comparator active group other than study medication. The safety profile of rozanolixizumab beyond 6 weeks remains uncertain and pending the results of the extension studies.

Study sponsor: UCB Pharma

N = 7 RCTs • Saccà F et al., 2023 • Systematic review, meta-analysis and network meta-analysis

POPULATION

Objective: To compare innovative treatments for gMG through a meta-analysis of already published or available data

N= 7 RCTs

Treatment efficacy was assessed after 26 weeks of eculizumab and ravulizumab, 28 days of efgartigimod, 43 days of rozanolixizumab, 12 weeks of zilucoplan, and 16, 24 or 52 weeks of rituximab treatment

METHODS

Database search of PubMed, Cochrane Library, American Academy of Neurology, European Academy of Neurology, Myasthenia Gravis Foundation of America (MGFA) International conference on Myasthenia and Related Disorders abstracts (all 1995-2022) for studies published after January 1, 1995 up to December 31, 2022

Inclusion: randomized controlled trials (RCTs), patients with gMG, with at least the Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores as outcome variables

RESULTS

Efficacy Outcome MG-ADL: No significant difference between complement inhibitors and anti-FcRn (p= 0.16 for sub-group differences). Efgartigimod observed to be the best treatment option, followed by rozanolixizumab at both doses (10 mg and 7 mg) among treatment groups with rituximab being the worst after placebo.

Efficacy Outcome QMG:
Efgartigimod observed to be the best treatment option, followed by rozanolixizumab 10 mg. Rozanolixizumab 10 mg was found to be consistently superior to ravulizumab (mean difference [MD] 2.76; 95% CI 0.64 to 4.88) and rituximab (MD 2.90; 95% CI 0.23 to 5.56)

Efficacy Outcome MGC: Although not statistically significant, the MGC score improvement was higher with anti-FcRn treatment, (MD −5.12 vs. −3.24; p= 0.12).

Efficacy Outcome MG-QoL15: Anti-FcRn treatment was associated with a greater effect versus complement inhibitors (MD −0.84 vs. −0.37; p= 0.01).

CONCLUSIONS

Authors' conclusions: Anti-complement and FcRn treatments both proved to be effective in MG patients, whereas rituximab did not show a significant benefit for patients. Within the limitations of this meta-analysis, including efficacy time points, FcRn treatments showed a greater effect on QMG score in the short term. Real-life studies with long-term measurements are needed to confirm our results.

Comment/Critique: Given the small number of studies, variable follow-up times, and lack of head-to-head comparison of data, results should be interpreted with caution.

Study sponsor: The study did not receive any financial support.

N = 532 • Li J et al., 2024 • Systematic review, meta-analysis

POPULATION

Objective: To investigate the efficacy and safety of FcRn inhibitors in patients with MG

N= 6 RCTs, 532 participants

METHODS

Database search of PubMed, EMBASE, Cochrane Library, ClinicalTrials.gov for studies published before May 18, 2023

Inclusion: RCT, participants aged ≥18 years, clinical gMG, intervention with FcRn inhibitor, primary outcome Myasthenia Gravis-Activities of Daily Living (MG-ADL), and secondary outcomes Quantitative Myasthenia Gravis (QMG), exploratory outcomes Myasthenia Gravis Composite (MGC) and 15-item revised Myasthenia Gravis Quality of Life (MGQoL15r), safety outcomes

Intervention: efgartigimod 10 mg/kg once a week (Q1W) for 11-26 weeks; rozanolixizumab 7 mg/kg Q1W for 99 days or 10 mg/kg Q1W for 6 weeks; batoclimab 340 mg or 680 mg Q1W for 6 weeks; nipocalimab 5 mg/kg Q4W, 30 mg/kg Q4W, 60 mg/kg Q2W for 113 days, and placebo administered at the same intervals

RESULTS

Efficacy Outcome MG-ADL:
FcRn inhibitors were more efficacious than placebo (MG-ADL: MD =−1.69 [95% CI: −2.35, −1.03], P<0.00001; MG-ADL responders: RR=2.01 [1.62, 2.48], P < 0.00001).

Efgartigimod compared to placebo:
MG-ADL responders (RR=2.22 (1.55, 3.19), P<0.0001). Rozanolixizumab compared to placebo: MG-ADL −2.11 [−3.00, −1.21, p< 0.00001], MG-ADL responders (RR=2.27 (1.60, 3.21), P<0.00001). Batoclimab MG-ADL −2.34 [−4.44, −0.24, p= 0.03]

Efficacy Outcome QMG:
FcRn inhibitors were more efficacious than placebo (MD =−2.45 [−4.35, −0.55],
P=0.01; I2= 80%), but not statistically significant for QMG responders (RR=1.40
[0.84, 2.32], P=0.20; I2= 71%)
Batoclimab reached statistical significance for QMG: MD −6.72 [−9.55, −3.89; p< 0.00001]
For QMG responders, rozanolixizumab MD 1.66 (1.23, 2.25; p= 0.001)) and batoclimab MD 2.14 (1.03, 4.48; p= 0.04)

Efficacy Outcome MGC:

CONCLUSIONS

Authors' Conclusions: FcRn inhibitors have good efficacy and safety in patients with MG. Among them, efgartigimod and batoclimab were effective without causing an increased safety risk. Rozanolixizumab, despite its superior efficacy, caused an increased incidence of adverse events. Current evidence does not suggest that nipocalimab is effective in patients with MG.

Comment/Critique: Meta-analysis included only 6 RCTs with limited number of patients. Data from different dosing groups were combined which may reduce credibility of the results. Subgroup analyses were performed according to drug type, differences in study design and patient characteristics may have contributed to differences.

Study sponsor: Article preparation supported by the Suzhou Health Talents Training Project (GSWS2019002), Natural Science Foundation of Jiangsu Province (BK20200203) and the Suzhou Health Talents Training Project (GSWS2020022).

FcRn inhibitors were superior to placebo (MGC: MD =−2.97 [−4.27, −1.67], P<0.00001). Rozanolixizumab MD =−3.52 [−5.14, −1.89], P<0.0001), batoclimab MD =−5.20 [−9.52, −0.88], P= 0.02)

Efficacy Outcome MG-QoL15:
FcRn inhibitors were superior to placebo MGQoL15r: MD=−2.52 [−3.54, −1.50], P<0.00001). Rozanolixizumab MD =−3.35 [−4.80, −1.90], P<0.00001), batoclimab MD =−4.46 [−7.48, −1.44], P= 0.004)

Safety:
No significant differences were found between FcRn inhibitors and placebo in AEs and SAEs (RR =1.05 [0.95, 1.15], P =0.33; RR=0.63 [0.34, 1.15], P = 0.13 respectively)
Rozanolixizumab showed a higher risk of AEs than the placebo (RR=1.18 [1.01, 1.40], P=0.04).

N = 872 • Ma Y et al., 2024 • Systematic review and meta-analysis

POPULATION

Objective: To comprehensively rank and compare the efficacy and safety of novel targeted drugs for the treatment of gMG

N= 13 studies, 872 subjects

METHODS

Database search of PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL) and ClinicalTrials.gov up to November 2022

Inclusion/Exclusion: RCTs or clinical controlled trial, feature at least one of the 10 desired drugs, describe change from baseline in quantitative myasthenia gravis score (QMGS) or number of adverse events (AE), >18 years old

Excluded if mean and standard deviation of QMGS changes or number of AEs not provided

batoclimab [1 trial], belimumab, CFZ533 (iscalimab), eculizumab [2 trials], efgartigimod [2 trials, nipocalimab, ravulizumab, rituximab, rozanolixizumab, zilucoplan

RESULTS

Reduction in QMGS from baseline: batoclimab (standardized mean difference [SMD], − 1.61; 95% credible interval [CrI], − 2.78, − 0.43) showed a significant advantage in reducing QMGS.

Remaining agents reduced QMGS from baseline but did not differ statistically compared with placebo: eculizumab (SMD, − 0.67; 95% CrI, − 1.43, 0.01), belimumab (SMD, − 0.38; 95% CrI, − 1.42, 0.66), CFZ533 (SMD, − 0.30; 95% CrI, − 1.33, 0.72), efgartigimod (SMD, − 0.34; 95% CrI, − 1.04, 0.34), nipocalimab (SMD, − 0.02; 95% CrI, − 1.04, 1.00), ravulizumab (SMD, -0.47; 95% CrI, − 1.35, 0.41), rituximab (SMD, − 0.35; 95% CrI, − 1.04, 0.34), rozanolixizumab (SMD, − 0.21; 95% CrI, − 1.20, 0.78), and zilucoplan (SMD, − 0.54; 95% CrI, − 1.56, 0.46)

Reduction in AE incidence: only batoclimab (RR, 0.19; 95% CrI, 0, 0.97) had lower incidence and was statistically significantly different compared to placebo.
Belimumab (RR, 0.85; 95% CrI, 0.57, 1.19), CFZ533 (RR, 0.95; 95% CrI, 0.72, 1.25), eculizumab (RR, 0.99; 95% CrI, 0.85, 1.21), and efgartigimod (RR, 0.93; 95% CrI, 0.76, 1.15) also led to a lower incidence of AEs but were not significantly different from placebo

CONCLUSIONS

Authors' conclusions: Batoclimab had the best efficacy and safety for the treatment of gMG and was ranked first out of the 10 targeted drugs included in this study. Eculizumab was ranked second, and nipocalimab had the worst efficacy. With the exception of batoclimab, the incidence of AEs for the remaining drugs was not statistically significantly different from placebo. We note, however, that wide CrIs reflect the uncertainty in this analysis owing to the small number of available studies and low numbers of study participants; moreover, batoclimab had the widest CrI of all drugs in this analysis. More well-designed studies with long-term follow-up are needed to further evaluate and compare the efficacy and safety of these drugs in the future.

Comment/Critique: Included limited studies that were mostly phase II and III, had small sample sizes, and follow up ranges from 4 to 52 weeks. Some of the agents are not FDA approved for MG.

Study sponsor: The authors did not receive support from any organization for the submitted work.

ADVERSE EFFECTS

Gastrointestinal	Diarrhea, nausea, abdominal pain
Hypersensitivity	Hypersensitivity reactions
Infection	Upper respiratory tract infections, urinary tract infections, herpes simplex
Local	Injection site reactions
Nervous system	Headache
Neuromuscular	Arthralgia
Other	Pyrexia

CONTRA-INDICATIONS

None

Interacting drug/class	Interaction	Clinical management
Medications that bind to human neonatal FC receptor (FcRn) (e.g., immunoglobulin products, monoclonal antibodies, antibody derivatives containing the human Fc domain of the IgG subclass)	May lower systemic exposures and reduce effectiveness of such medications	Closely monitor for reduced effectiveness of medications that bind to human neonatal Fc receptor. When concomitant long-term use of such medications is essential, consider discontinuing rozanolixizumab-noli and using alternative therapies.

STORAGE

How Supplied: Rystiggo® rozanolixizumab-noli injection: 280 mg/2 mL (140 mg/mL) single-dose glass vial in a carton: NDC 50474-980-79

Storage and Stability:

Store vials refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light until the time of use. Do not freeze. Do not shake.

If needed, vials may be stored at room temperature up to 77°F (25°C) for a single period of up to 30 days in the original carton to protect the vial from light. Once a vial has been stored at room temperature, it should not be returned to the refrigerator. The discard date is 30 days after removal of the vial from the refrigerator. Write the discard date in the space provided on the carton. Discard the vial if not used within 30 days or if the expiration date has passed, whichever occurs first.

SAFETY CONSIDERATIONS

BOXED WARNINGS

None

WARNINGS & PRECAUTIONS

- **Infections:** Delay administration to patients with an active infection. Monitor for signs and symptoms of infection in patients treated with Rystiggo®. If a serious infection occurs, administer appropriate treatment and consider withholding until the infection has resolved.

- **Aseptic Meningitis:** Serious events of aseptic meningitis have been reported. Monitor for symptoms; diagnostic workup and treatment should be initiated according to the standard of care.

- **Hypersensitivity Reactions**: Hypersensitivity reactions, including angioedema and rash, have occurred. If a hypersensitivity reaction occurs, discontinue the infusion and institute appropriate therapy.

Renal impairment	No dedicated pharmacokinetic study has been conducted in patients with renal impairment. Renal impairment is not expected to affect the pharmacokinetics of rozanolixizumab-noli. Based on a population pharmacokinetic analysis, which included participants with mild to moderate renal impairment, renal function (estimated glomerular filtration rate [eGFR] 38–161 mL/min/1.73 m2) had no clinically significant effect on rozanolixizumab-noli apparent clearance. No dose adjustment is required in patients with renal impairment.
Hepatic impairment	No dedicated pharmacokinetic study has been conducted in patients with hepatic impairment. Hepatic impairment is not expected to affect the pharmacokinetics of rozanolixizumab-noli.
Geriatrics	Clinical studies of Rystiggo® did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger adult patients.
Pediatrics	Safety and effectiveness in pediatric patients have not been established.
Reproductive potential	Animal studies using doses 30 times the maximum recommended human dose resulted in no adverse effects in sperm parameters or estrus cyclicity.
Pregnancy	There are limited data on Rystiggo® use in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.
Lactation	There are no data on the presence of rozanolixizumab-noli in human milk, the effects on the breastfed infant, or the effects on milk production.

DOSAGE & ADMINISTRATION

Recommended vaccination: Because Rystiggo® causes transient reduction in IgG levels, immunization with live-attenuated or live vaccines is not recommended during treatment. Evaluate the need to administer age-appropriate immunizations according to immunization guidelines before initiation of a new treatment cycle with Rystiggo®.

- The recommended dosage of Rystiggo® is based on body weight:

Body Weight of Patient	Dose	Volume to be Infused
< 50 kg	420 mg	3 mL
50 kg to < 100 kg	560 mg	4 mL
≥ 100 kg	840 mg	6 mL

  - Administer the recommended dosage as a subcutaneous infusion using an infusion pump at a rate of up to 20 mL/hour once weekly for 6 weeks.
  - Administer subsequent treatment cycles based on clinical evaluation. The safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established.
  - If a scheduled dose is missed, Rystiggo® may be administered up to 4 days after the scheduled time point. Thereafter, resume the original dosing schedule until the treatment cycle is completed.

Administration

Rystiggo® is for subcutaneous administration only using an infusion pump. It is recommended to use pumps where administered volume can be pre-set as each vial contains excess volume for priming of the infusion line.

The following criteria are recommended for administration of Rystiggo®:

- Syringe pump occlusion alarm limits should be at the maximum setting
- Administration tubing length should be 61 cm or shorter
- Infusion set with a needle of 26 gauge or larger should be used

Instructions before preparing and administering Rystiggo®:

- Use aseptic technique
- Prior to use, allow vials to reach room temperature for about 30 minutes. Do not use heating devices. Keep vial in original container to protect from light until ready to use. Do not shake.
- Infuse within 4 hours of puncturing the vial. Administer immediately after priming the infusion set.
- Visually inspect for particulate matter and discoloration. Solution should be pale brownish-yellow, clear to slightly opalescent. Do not use if liquid looks cloudy, contains foreign particles, or has changed color.
- Use transfer needles to fill the syringe.
- Remove the needle from syringe and attach infusion set to syringe
- Follow device manufacturer's instruction to prepare pump and prime tubing
- Choose an infusion site in lower right or lower left part of abdomen below the navel and clean with alcohol wipe. Do not infuse where skin is tender, bruised, red or hard. Avoid infusing into tattoos, scars, or stretch marks. Rotate infusion sites for subsequent administrations.
- Insert infusion set needle into infusion site and secure needle to skin with sterile gauze and tape or transparent dressing.
- Infuse at constant flow rate of up to 20 mL/hr
- Monitor patient during administration and for 15 minutes after completion for hypersensitivity reactions. If hypersensitivity reaction occurs during administration, discontinue and institute appropriate supportive measures.
- When infusion is complete, do not flush infusion line as volume of infusion has been adjusted taking into account the losses in the line.

Each vial is for one time use and does not contain preservatives. Discard any remaining solution.

REFERENCES

1. Rystiggo rozanolixizumab injection, solution. Prescribing information. UCB Inc. June 2023.
2. U.S. Food & Drug Administration. Purple Book Database of Licensed Biological Products. Last updated April 11, 2024. Accessed May 2, 2024
3. Beloor Suresh A, Asuncion RMD. Myasthenia Gravis. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559331/
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis: 2020 update. Neurology. 2021;96(3):114-122. doi:10.1212/WNL.0000000000011124
5. Wiendl H, Abicht A, Chan A, et al. Guideline for the management of myasthenic syndromes. Ther Adv Neurol Disord. 2023;16:17562864231213240. Published 2023 Dec 26. doi:10.1177/17562864231213240
6. Gilhus NE, Andersen H, Andersen LK, et al. Generalized myasthenia gravis with acetylcholine receptor antibodies: A guidance for treatment. Eur J Neurol. 2024;31(5):e16229. doi:10.1111/ene.16229
7. Bril V, Benatar M, Andersen H, et al. Efficacy and Safety of Rozanolixizumab in Moderate to Severe Generalized Myasthenia Gravis: A Phase 2 Randomized Control Trial. Neurology. 2021;96(6):e853-e865. doi:10.1212/WNL.0000000000011108
8. Bril V, Drużdż A, Grosskreutz J, et al. Safety and efficacy of rozanolixizumab in patients with generalized myasthenia gravis (MycarinG): a randomized, double-blind, placebo-controlled, adaptive phase 3 study. Lancet Neurol. 2023;22(5):383-394. doi:10.1016/S1474-4422(23)00077-7
9. Saccà F, Pane C, Espinosa PE, Sormani MP, Signori A. Efficacy of innovative therapies in myasthenia gravis: A systematic review, meta-analysis and network meta-analysis. Eur J Neurol. 2023;30(12):3854-3867. doi:10.1111/ene.15872
10. Li J, Wu X, Chu T, et al. The efficacy and safety of FcRn inhibitors in patients with myasthenia gravis: a systematic review and meta-analysis. J Neurol. 2024;271(5):2298-2308. doi:10.1007/s00415-024-12247-x
11. Ma Y, Nie X, Zhu G, Qi W, Hao L, Guo X. The Efficacy and Safety of Different Targeted Drugs for the Treatment of Generalized Myasthenia Gravis: A Systematic Review and Bayesian Network Meta-analysis. CNS Drugs. 2024;38(2):93-104. doi:10.1007/s40263-024-01062-7
12. Merative™ Micromedex® Red Book® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com; Accessed May 2, 2024