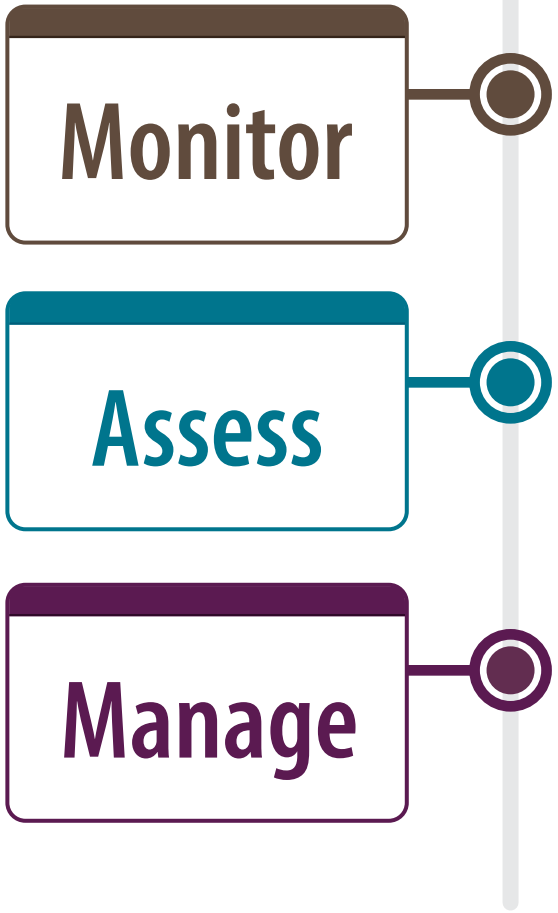
Distinguishing drug eruption from disease progression



Indication

POTELIGEO (mogamulizumab-kpkc) injection for intravenous infusion is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.

Important Safety Information

Warnings and Precautions

Dermatologic toxicity: Monitor patients for rash throughout the course of treatment. For patients who experienced dermatologic toxicity in Trial 1, the median time to onset was 15 weeks, with 25% of cases occurring after 31 weeks. Interrupt POTELIGEO for moderate or severe rash (Grades 2 or 3). Permanently discontinue POTELIGEO for life-threatening (Grade 4) rash or for any Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN).

Please see additional Important Safety Information throughout and full Important Safety Information on page 7.
See the accompanying full Prescribing Information.

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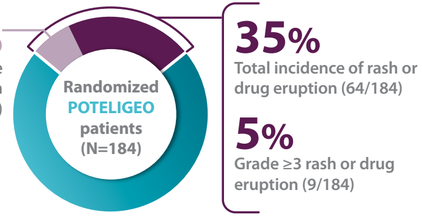
Rash or drug eruption can be expected—and managed during treatment[1]

Drug eruptions may look like disease progression

Distinguishing between the two may help prevent premature discontinuation of therapy.[2,3]

Drug eruption in MAVORIC[1,a]

- Drug eruption was the most common adverse reaction
- Some patients chose to continue POTELIGEO once drug eruption was resolved



Infusion reactions were common in MAVORIC; administration of diphenhydramine and acetaminophen is recommended prior to the first infusion and subsequent infusions if an infusion reaction occurs.

[a] MAVORIC was the registrational trial for POTELIGEO, a phase 3 randomized controlled study of POTELIGEO vs an active comparator.[1]

Important Safety Information *(continued)*

Warnings and Precautions *(continued)*

Infusion reactions: Most infusion reactions occur during or shortly after the first infusion. Infusion reactions can also occur with subsequent infusions. Monitor patients closely for signs and symptoms of infusion reactions and interrupt the infusion for any grade reaction and treat promptly. Permanently discontinue POTELIGEO for any life-threatening (Grade 4) infusion reaction.

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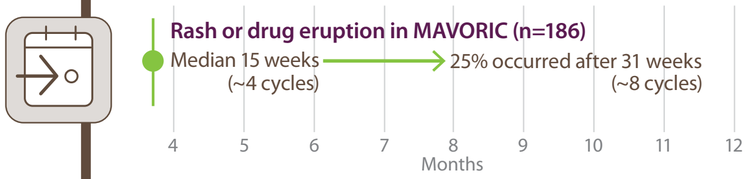
Monitor

Patients should be monitored for rash throughout the treatment course[1]

Time to onset is variable[1]



Adverse reactions (AR) can occur at any time during treatment.[1]

If an AR occurs, always assess the benefit-risk.[1]

Appearance and affected areas are variable[1]

More commonly seen in MAVORIC[1]:

- Papular or maculopapular rash
- Lichenoid rash
- Spongiotic or granulomatous dermatitis
- Morbilliform rash

Other presentations included (but not limited to):

- Scaly plaques
- Pustular eruption
- Folliculitis
- Non-specific dermatitis
- Psoriasiform dermatitis

Important Safety Information *(continued)*

Warnings and Precautions *(continued)*

Infections: Monitor patients for signs and symptoms of infection and treat promptly.

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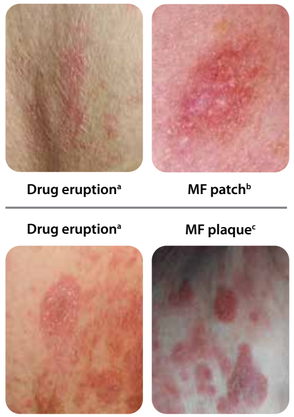
Assess

Drug eruption and disease progression can look very similar

Skin biopsy is recommended for differential diagnosis[1]

Peripheral blood flow cytometry and skin biopsy with T-cell receptor sequencing should also be considered.[2]

Dermatopathology consult can provide definitive diagnosis and help determine treatment path[2,3]



Pictures are intended to be an example. Actual presentation can vary depending on individual patient factors.

[a] Photo used with permission from *JAMA Dermatol*.
[b] Photo used with permission from *Oncology*.
[c] Photo used with permission from *Cancer Management and Research 2019:11 2241-2251*. Originally published by and used with permission from Dove Medical Press Ltd.

Important Safety Information *(continued)*

Warnings and Precautions *(continued)*

Autoimmune complications: Interrupt or permanently discontinue POTELIGEO as appropriate for suspected immune-mediated adverse reactions. Consider the benefit/risk of POTELIGEO in patients with a history of autoimmune disease.

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Manage

Recommendations for managing dermatologic toxicity[1]

Grade 1 (mild)	Grade 2 or 3 (moderate or severe)	Grade 4 (life-threatening)
Treatment with POTELIGEO may continue	**Interrupt POTELIGEO**	**Permanently discontinue for life-threatening rash or for any SJS or TEN**
Consider treating rash, including drug eruption, with topical corticosteroids.	Administer at least 2 weeks of topical corticosteroids. If rash improves to ≤grade 1, POTELIGEO may be resumed.	For suspected SJS or TEN, stop POTELIGEO; do not resume treatment unless SJS or TEN have been excluded and the cutaneous reaction has been resolved to ≤grade1.[a]

[a] Less than 1% of all POTELIGEO-treated patients in clinical trials experienced grade 4 skin adverse reactions; SJS occurred in <1% of patients.[1]
SJS=Stevens-Johnson syndrome; TEN=toxic epidermal necrolysis

Important Safety Information *(continued)*

Warnings and Precautions *(continued)*

Complications of allogeneic HSCT after POTELIGEO: Increased risks of transplant complications have been reported in patients who received allogeneic HSCT after POTELIGEO. Follow patients closely for early evidence of transplant-related complications.

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Multidisciplinary team approach is recommended for managing patients with MF and SS

Dermatologic expertise throughout the course of treatment can help distinguish drug eruption from disease progression.[2]

Important Safety Information *(continued)*

Adverse Reactions

The most common adverse reactions (reported in ≥10% of patients) with POTELIGEO in the clinical trial were rash, including drug eruption (35%), infusion reaction (33%), fatigue (31%), diarrhea (28%), drug eruption (24%), upper respiratory tract infection (22%), musculoskeletal pain (22%), skin infection (19%), pyrexia (17%), edema (16%), nausea (16%), headache (14%), thrombocytopenia (14%), constipation (13%), anemia (12%), mucositis (12%), cough (11%), and hypertension (10%).

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You are encouraged to report suspected adverse reactions to Kyowa Kirin, Inc. at 1-844-768-3544 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information.

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References: 1. POTELIGEO [package insert]. Kyowa Kirin Inc., Bedminster, NJ USA. **2.** Chen L, Carson KR, Staser KW, Mehta-Shah N, Schaffer A, Rosman IS, Musiek A. Mogamulizumab-associated cutaneous granulomatous drug eruption mimicking mycosis fungoides but possibly indicating durable clinical response. *JAMA Dermatol*. 2019;155:968-971. **3.** Poligone B, Querfield C. Management of advanced cutaneous T-cell lymphoma: role of the dermatologist in the multidisciplinary team. *Br J Dermatol*. 2015;173:1081-1083.

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PM-US-POT-0308 October 2020

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