# *Transitioning or Switching to Vabysmo from IVT Anti-VEGF Therapies*

This article responds to your request for information on Vabysmo® (faricimab) and switching over from another therapy. This response was developed according to the principles of evidence-based medicine and summarizes data from the Vabysmo clinical development program, including Phase 3 studies.

## In brief

- Roche does not provide any specific recommendations for dosing when switching from previous anti-VEGF therapies to Vabysmo, beyond the dosing recommendations in the local prescribing information.
    - The recommended dosing of Vabysmo for both DME and nAMD is 6 mg via IVT injection every 4 weeks for the first 4 doses, followed by 6 mg via IVT injection at intervals of up to every 16 weeks.
- Roche does not provide any recommendations for when to switch from previous anti-VEGF therapies to Vabysmo. However, the treatment with previous therapy was accounted for during enrolment of the Phase 3 clinical studies.
    - Patients with DME who previously received IVT anti-VEGF agents were eligible for study entry only if the treatment was not administered in the prior 3 months.
    - Only treatment-naive patients with nAMD were enrolled in the studies. Patients who previously received anti-VEGF treatment were not eligible for study entry.
- A period of approximately 5 times the elimination half-life is generally considered sufficient for washout.

## Abbreviations

DME=diabetic macular edema
IVT=intravitreal
nAMD=neovascular age-related macular degeneration
Q4W=every 4 weeks
Q8W=every 8 weeks
Q12W=every 12 weeks
Q16W=every 16 weeks
VEGF=vascular endothelial growth factor

## Dosing when switching from previous IVT anti-VEGF therapy to Vabysmo

Roche does not provide any specific recommendations for dosing when switching from previous anti-VEGF therapies to Vabysmo, beyond the dosing recommendations in the local prescribing information.

The recommended dosing of Vabysmo for both DME and nAMD is 6 mg via IVT injection every 4 weeks for the first 4 doses, followed by 6 mg via IVT injection at intervals of up to every 16 weeks.[1]

Monitoring between the dosing visits should be scheduled based on the patient's status and at the physician's discretion.[1]

## Rationale for Vabysmo initial 6 mg Q4W dosing schedule

The 6 mg dose was based on data from preclinical models, clinical outcomes from Phase 1[2] and 2[3-5] studies and clinical pharmacokinetic and pharmacodynamic assessments.

For Phase 3 studies, the 6 mg dose was selected to maximize the potential for a durable treatment effect on the basis of a pharmacokinetic and pharmacodynamic model.[6]

### Phase 3 YOSEMITE and RHINE studies in DME patients

YOSEMITE (NCT03622580) and RHINE (NCT03622593) were two identical, randomized, multicenter, double-masked, global Phase 3 trials designed to evaluate the efficacy and safety of Vabysmo compared with aflibercept in patients with DME.[7]

The two Vabysmo treatment groups received either four initial 6 mg doses Q4W up to Week 12, followed by dosing interval adjustments according to a personalized treatment interval or six initial 6 mg doses Q4W up to Week 20, followed by a dosing interval increase to Q8W.[7]

### Phase 3 LUCERNE and TENAYA studies in nAMD patients

TENAYA (NCT03823287) and LUCERNE (NCT03283300) were two identical, randomized, multicenter, double-masked, global Phase 3 trials to evaluate the efficacy, safety, and durability of Vabysmo compared with aflibercept in patients with nAMD.[8]

The Vabysmo treatment group received four initial 6 mg doses Q4W, up to Week 12, then dosing intervals were increased to either Q8W, Q12W or Q16W through Week 60 based on protocol-defined disease activity criteria.[8]

## Timing of switch from previous IVT anti-VEGF therapy to Vabysmo

Roche does not provide any recommendations for when to switch from previous anti-VEGF therapies to Vabysmo.

However, the treatment with previous therapy was accounted for during enrolment of the Phase 3 clinical studies.

### Eligibility criteria in the YOSEMITE and RHINE studies in DME patients

Patients who previously received IVT anti-VEGF agents were eligible for study entry only if the treatment was not administered in the prior 3 months.[9,10]

### Eligibility criteria in the TENAYA and LUCERNE studies in nAMD patients

Only treatment-naive patients were enrolled in the studies. Patients who previously received anti-VEGF treatment were not eligible for study entry.[11,12]

### Washout period of IVT anti-VEGF therapy

A period of approximately 5 times the elimination half-life is generally considered sufficient for washout.[13,14] The appropriate washout period will depend on the vitreous elimination half-life of the previous IVT anti-VEGF drug. We refer the interested reader to the prescribing information of the respective drugs for more information.

## References


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