Product Sheet - Mvasi

Mvasi is a biosimilar of bevacizumab developed by Amgen. It is indicated for the treatment of various types of cancer, including colorectal, lung, glioblastoma, renal, and breast cancer. It works by inhibiting angiogenesis, which is the growth of new blood vessels that feed tumors. It offers a more accessible therapeutic option while maintaining the efficacy and safety of the reference drug.

Frequently Asked Questions

1. What is the clinical evidence supporting the approval of Mvasi?

Mvasi has demonstrated biosimilarity in a phase III study in patients with non-small cell lung cancer, showing comparable results to the reference product.

2. Have direct comparative studies between Mvasi and Avastin been conducted in terms of efficacy and safety?

Yes, the phase III MAPLE study directly compared the efficacy and safety of Mvasi with Avastin in patients with non-small cell lung cancer.

3. How does the immunogenicity of Mvasi compare with that of Avastin?

The immunogenicity profiles are similar between Mvasi and the reference product, with no significant differences in the incidence of neutralizing antibodies.

4. Has Mvasi shown a reduction in tumor growth comparable to Avastin in preclinical studies?
Yes, preclinical studies showed tumor growth inhibition with Mvasi comparable to the reference product.

5. What is Amgen's experience in manufacturing biosimilars like Mvasi?

Amgen has extensive experience in biotechnology, applied to the development of Mvasi with strong quality controls and a commitment to reliable delivery and supply.

6. Does Amgen provide any post-sale support or educational programs for Mvasi?

Amgen offers an active pharmacovigilance program, support for user experience, and tailored training sessions.

7. Does Mvasi offer any advantages in terms of cost or access for patients?

Mvasi is designed to offer a competitive price, which could optimize cost-efficiency for institutions and improve patient access.

8. Is Mvasi approved for the same indications as Avastin?

Yes, Mvasi is approved for the same clinical indications as Avastin, such as metastatic colorectal cancer and non-small cell lung cancer.

9. How is Mvasi administered and what is the recommended dosage?

Mvasi is administered similarly to Avastin, with specific dosages according to the indication, for example, 5 mg/kg every 2 weeks or 15 mg/kg every 3 weeks for certain cancers.

10. What is the manufacturing process for Mvasi and how does Amgen ensure product quality?

Mvasi is produced in state-of-the-art facilities following rigorous manufacturing processes with a strong emphasis on product quality and consistency.

11. What specific results from the MAPLE study can support the treatment decision?

The MAPLE study confirmed that Mvasi is clinically biosimilar to the reference product, with similar objective response rates and equivalence margins.

12. What type of monitoring and follow-up is necessary for patients receiving Mvasi?

Monitoring and follow-up for patients receiving Mvasi follow the same clinical guidelines as the reference product, focusing on efficacy and safety.

13. Has Mvasi shown differences in pharmacokinetic or pharmacodynamic profiles compared to

Avastin?

Studies have shown comparable pharmacokinetic and pharmacodynamic profiles between Mvasi and Avastin.

14. Does Amgen have a specific commitment to the supply and availability of Mvasi?

Amgen is firmly committed to delivering its products, including Mvasi, to every patient at all times.

This includes a robust distribution and manufacturing network and a proactive risk mitigation approach to ensure supply.

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17. What kind of updated information does Amgen provide about Mvasi and how can I access it?

Amgen offers access to recent publications, webinars, and conferences on Mvasi through its medical professionals' portal.

18. What level of post-sale support does Amgen offer to physicians prescribing Mvasi?

Amgen has a dedicated customer support team to provide information and assistance about Mvasi after the sale.

19. Are there opportunities for continuous education offered by Amgen about biosimilars like Mvasi?

Yes, Amgen offers continuous education programs that include webinars, workshops, and online

resources.

- 20. How can I compare the outcomes of patients with Mvasi versus other treatments?

 Amgen provides clinical study data and practical case studies illustrating patient outcomes with Mvasi.
- 21. Is there any patient support program or educational material available for those starting with Mvasi?

Amgen offers educational materials and support programs for patients starting treatment with Mvasi.

22. What educational resources does Amgen offer to facilitate the transition to Mvasi in my multidisciplinary team?

Amgen provides training materials and sessions designed for multidisciplinary teams on the use of Mvasi.

- 23. What kind of follow-up does Amgen offer after introducing Mvasi into my clinical practice?

 Amgen offers ongoing follow-up and support after adopting Mvasi, including reviewing efficacy and safety in real-world practice.
- 24. Can Amgen facilitate access to testimonials from other physicians who have prescribed Mvasi?

 Amgen can provide access to testimonials and experiences from other medical professionals who have used Mvasi.
- 25. How does Amgen ensure a consistent supply of Mvasi?

Amgen has established policies and processes to ensure the consistent production and supply of Mvasi.

26. What cost-effectiveness strategies does Amgen offer for the implementation of Mvasi in

institutions with limited budgets?

Amgen works with institutions to offer cost-effectiveness strategies, which may include pricing options, discounts, and assistance in acquiring Mvasi.

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27. Is Mvasi really as effective as Avastin?

Yes, studies have shown that Mvasi is biosimilar to Avastin, meaning it has comparable efficacy, safety, and purity.

28. I'm concerned about side effects in my patients.

We understand your concern. The safety and tolerability profiles of Mvasi are similar to those of Avastin, as demonstrated in clinical studies.

29. How can I be sure of the quality and consistency of Mvasi?

Amgen follows rigorous manufacturing standards to ensure the quality and consistency of Mvasi, backed by years of experience in biotechnology.

30. What if my patients do not respond well to the treatment change?

This is a valid concern. We recommend close monitoring during the transition, and Amgen offers support for any concerns or needs that arise during this period.

31. Can Mvasi really offer an advantage in terms of costs?

Absolutely. Mvasi is designed to be a more economical option, which can help reduce overall treatment costs for your patients and institution.