U NOVARTIS

TAF + MEK ® Glioma

Image



Image



• <u>Indication</u>

• <u>Prognosis</u>

• Dosing

TAFINLAR + MEKINIST is the first treatment regimen for low- and glioma with BRAF V600E mutat	high-grade paediatric
[†] As of July 2025.	
Image	

Low-grade glioma^{1,2}

Treatment of paediatric patients ≥1 year of age with low-grade glioma with a BRAF V600E mutation who require systemic therapy

Learn more

Image

High-grade glioma^{1,2}

Treatment of paediatric patients ≥1 year of age with high-grade glioma with a BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options

Learn more

• Indication

• <u>Prognosis</u>

• Dosing

BRAF V600E+ mutation is common in p	paediatric
glioma and typically has a poor progne	
Image	

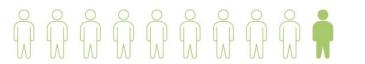
Low-grade glioma

Up to 20% paediatric of low-grade glioma patients will have a BRAF V600E mutation³



High-grade glioma

Up to 10% of paediatric high-grade glioma patients will have a BRAF V600E mutation⁴



Poorer response to current standard of care

Paediatric patients with glioma and a BRAF V600E mutation have poorer response to chemotherapy, resulting in shorter PFS and OS⁵



Image

Test early for the BRAF V600E+ mutation via genetic testing to give paediatric patients and their caregivers new hope for low- and high-grade glioma treatment

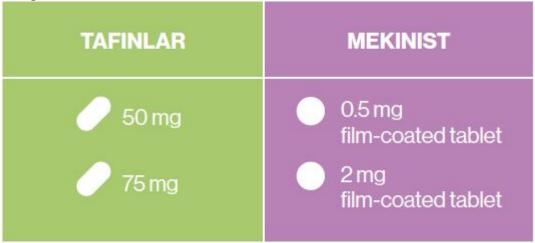
• Indication

• <u>Prognosis</u>

• Dosing

Flexible, weight-based dosing with paediatric-friendly formulations
TAFINLAR + MEKINIST is an oral regimen with weight-based dosing for paediatric patients (aged ≥ 1 year) with low- and high-grade glioma from 8 kg. ^{1,2} TAFINLAR is available in capsules or dispersible tablet forms, and MEKINIST is available as tablets or powder for oral solution. ^{1,2}
Capsule and tablet formulation (patients weighing ≥26 kg) ^{1,2}

Image



Oral suspension and solution formulation (patients weighing $\geq 8 \text{ kg}$)^{1,2}

Image

TAFINLAR	MEKINIST
10 mg dispersible tablet [†]	1 0.05 mg/mL powder for oral solution [†]

Dosing for capsules and tablets administration (patients weighing ≥26 kg)

Recommended weight-based dosing and dose reductions for TAFINLAR capsule administration¹

TAFINLAR

Body Weight	Recommended Paediatric Dose (BID)	First Dose Reduction (BID)	Second Dose Reduction (BID)	Third Dose Reduction(BID)
26 to 37 kg	75 mg (one 75 mg capsule)	50 mg	% -	7 8
38 to 50 kg	100 mg (two 50 mg capsules)	75 mg	50 mg	-3
≥51 kg	150 mg (two 75 mg capsules)	100 mg	75 mg	50 mg

BID, twice daily

Permanently discontinue if unable to tolerate maximum of three dose reductions or a TAFINLAR 50 mg capsule orally twice daily¹

Recommended weight-based dosing and dose reductions for MEKINIST tablet administration²

Image MEKINIST

Body Weight	Recommended Paediatric Dose (QD)	First Dose Reduction (QD)	Second Dose Reduction (QD)
26 to 37 kg	1 mg (two 0.5-mg tablets)	0.5 mg	
38 to 50 kg	1.5 mg (three 0.5-mg tablets)	1mg	0.5 mg
≥51 kg	2 mg (one 2-mg tablet)	1.5 mg	1mg

QD, once daily

Permanently discontinue if unable to tolerate a maximum of two dose reductions²

Dosing for oral suspension and oral solution administration (patients weighing ≥8 kg)

Recommended weight-based dosing and dose reductions for TAFINLAR dispersible tablets¹

Image

TAFINLAR

Body Weight (kg)	Daily Dose (BID)	# of 10 mg Tablets (BID)	First Reduction (# of 10 mg Tablets, BID)	Second Reduction (# of 10 mg Tablets, BID)	Third Reduction (# of 10 mg Tablets, BID)
8 to 9	20 mg	2	1	-	-
10 to 13	30 mg	3	2	1	_
14 to 17	40 mg	4	3	2	1
18 to 21	50 mg	5	3	2	1
22 to 25	60 mg	6	4	3	2
26 to 29	70 mg	7	5	4	2
30 to 33	80 mg	8	5	4	3
34 to 37	90 mg	9	6	5	3
38 to 41	100 mg	10	7	5	3
42 to 45	110 mg	11	7	6	4
46 to 50	130 mg	13	9	7	4
≥51	150 mg	15	10	8	5

BID, twice daily

Permanently discontinue if unable to tolerate a maximum of 3 dose reductions or a TAFINLAR 10 mg dispersible tablet orally twice daily 1

Recommended weight-based dosing and dose reductions for MEKINIST powder for oral solution²

Image MEKINIST

Body Weight (kg)	Recommended Dose Total Volume (QD)	First Dose Reduction (QD)	Second Dose Reduction (QD)
8	6 mL (0.3 mg)	5 mL	3 mL
9	7 mL (0.35 mg)	5 mL	4 mL
10	7 mL (0.35 mg)	5 mL	4 mL
11	8 mL (0.4 mg)	6 mL	4 mL
12 to 13	9 mL (0.45 mg)	7mL	5 mL
14 to 17	11 mL (0.55 mg)	8 mL	6 mL
18 to 21	14 mL (0.7 mg)	11 mL	7mL
22 to 25	17 mL (0.85 mg)	13 mL	9 mL
26 to 29	18 mL (0.9 mg)	14 mL	9 mL
30 to 33	20 mL (1 mg)	15 mL	10 mL
34 to 37	23 mL (1.15 mg)	17 mL	12 mL
38 to 41	25 mL (1.25 mg)	19 mL	13 mL
42 to 45	28 mL (1.4 mg)	21mL	14 mL
46 to 50	32 mL (1.6 mg)	24 mL	16 mL
≥51	40 mL (2 mg)	30 mL	20 mL

QD, once daily

Permanently discontinue if unable to tolerate a maximum of two dose reductions²

Image

Click here to learn more about TAFINLAR + MEKINIST for low-grade glioma

Image

Click here to learn more about TAFINLAR + MEKINIST for high-grade glioma

TAFINLAR and MEKINIST PBS Information: Authority Required. Please refer to PBS Schedule for full authority information for products.

▼ These medicinal products are subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

For Australian healthcare professionals only. Please review Product Information before prescribing. For TAFINLAR Product Information, please <u>click here</u>. For MEKINIST Product Information, please <u>click here</u>. Alternatively, contact med info on 1800 671 203 to access the full Product Information.

Footnotes and References

Abbreviations: AE, adverse event; **CI**, confidence interval; **HR**, hazard ratio; **ORR**, objective response rate; **OS**, overall survival; **PBS**, Pharmaceutical Benefits Scheme; **PFS**, progression-free survival.

References: 1. TAFINLAR (dabrafenib) Australian approved product information. **2.** MEKINIST (trametinib) Australian approved product information. **3.** Bouffet E, et al. N Engl J Med. 2023;389:1108–1120. **4.** Hargrave DR, et al. J Clin Oncol. 2023;41(28):5174–5183. **5.** Lassaletta A, et al. J Clin Oncol. 2017;35(25):2934–2941.

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Adverse events should be reported.

Adverse events and product complaints should also be reported to Novartis.

For Medical Enquiries, Information Services, Adverse Events and Product Complaints please contact: 1800 671 203 or medinfo.phauno@novartis.com

Colleagues are available from 9:00 to 17:00 from Monday to Friday.

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