DOSING & ADMINISTRATION GUIDE

BRAFTOVI® ▼ (encorafenib) + MEKTOVI® ▼ (binimetinib)

INDICATION

BRAFTOVI® (encorafenib) in combination with MEKTOVI® (binimetinib) is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a *BRAF*^{V600} mutation.

Recommended dosing[1,2] Click here

Dosage forms and strengths[1,2] Click here

Recommended dose adjustments[1,2] Click here

Choosing doses to order in the pharmacy[1,2] Click here

This material is intended to provide information on BRAFTOVI®+MEKTOVI® dosing and administration, and facilitate the conversion between the dose levels and corresponding amount of product packs.

This material is based on EU Product Information and does not replace the Summaries of Product Characteristics (SmPC). Before prescribing, always refer to the SmPC approved in your country.

▼**These medicinal products are subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects via your national reporting system and/or to the Pharmacovigilance department of Pierre Fabre laboratories (https://www.pierre-fabre.com/en/pharmacovigilance).**

1. BRAFTOVI® Summary of Product Characteristics. Pierre Fabre Médicament, 2022. https://www.ema.europa.eu/en/documents/product-information/braftovi-epar-product-information_en.pdf

2. MEKTOVI® Summary of Product Characteristics. Pierre Fabre Médicament, 2022. https://www.ema.europa.eu/en/documents/product-information/mektovi-epar-product-information_en.pdf

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HQ-BRH-12-21-2100003 V2.0

Recommended dosing[1,2]

BRAFTOVI® (encorafenib) + MEKTOVI® (binimetinib)

Confirm the presence of *BRAF*^{V600} mutation before treatment.

BRAFTOVI® + MEKTOVI® may be taken with or without food, except grapefruit juice

Swallow doses whole with water

No refrigeration requirement; store BRAFTOVI® below 30°C

Uninterrupted dosing schedule

ONE DOSE PER DAY

(in the morning OR at night)

BRAFTOVI®
450 mg[a]
6x 75 mg

Your patients should adopt a routine for taking BRAFTOVI® + MEKTOVI® that fits their lifestyle

MEKTOVI®
45 mg
3x 15 mg
1st DOSE

12 HOURS APART

MEKTOVI®
45 mg
3x 15 mg
2nd DOSE

Treatment with BRAFTOVI® + MEKTOVI® should be continued until the patient no longer derives benefit or the development of unacceptable toxicity.

Patients should not take a missed dose of:

6 hours — MEKTOVI® within **6 hours** of the next dose

12 hours — BRAFTOVI® within **12 hours** of the next dose

In case of vomiting after administration of BRAFTOVI® + MEKTOVI®, the patient should not take an additional dose and should take the next scheduled dose.

BRAFTOVI® + MEKTOVI® are not recommended during pregnancy, breast-feeding and in women of childbearing potential not using contraception; it is unknown whether BRAFTOVI® or MEKTOVI® or their metabolites are excreted in human milk.

A risk to the newborns/infants cannot be excluded.

Please refer to the Summaries of Product Characteristics

Recommended dose adjustments[1,2]

BRAFTOVI® + MEKTOVI® are indicated to be taken in combination.

The management of adverse reactions may require dose reduction, temporary interruption, or treatment discontinuation.

BRAFTOVI® (encorafenib)

Starting dose	First reduction	Second reduction	Subsequent modification[a]	
450 mg QD	300 mg QD	225 mg QD	100 mg QD	PERMANENTLY DISCONTINUE
6x 75 mg	4x 75 mg	3x 75 mg	2x 50 mg (limited data)	

MEKTOVI® (binimetinib)

Starting dose	First reduction[b]	
45 mg BID	30 mg BID	PERMANENTLY DISCONTINUE
3x 15 mg	2x 15 mg	

Dose interruption and discontinuation

BRAFTOVI		MEKTOVI
Temporarily interrupted	→	Interrupt
Reduce BRAFTOVI® to 300 mg QD during the time MEKTOVI® is interrupted	←	Temporarily interrupted
Permanently discontinued	↔	Permanently discontinued

If either BRAFTOVI® or MEKTOVI® is permanently discontinued, then discontinue both treatments

Dose modifications are recommended to manage certain adverse reactions. For additional information, please see section 4.2 of the full Summaries of Product Characteristic of BRAFTOVI® and MEKTOVI®.

[a]There are limited data for dose reduction to 100 mg QD. If unable to tolerate 100 mg QD, permanently discontinue BRAFTOVI®.[1]
[b]If unable to tolerate 30 mg BID, permanently discontinue MEKTOVI®.[1]

BID: twice daily
QD: once daily

Please refer to the Summaries of Product Characteristics

Dosage forms and strengths[1,2]

BRAFTOVI® (encorafenib) is supplied as 75 mg and 50 mg capsules

Packs of 42 x 1 capsules

For patients treated at full dose or undergoing dose reduction at 300 mg or 225 mg

7 peelable blisters
of 6 capsules each

Packs of 28 x 1 capsules

For patients undergoing dose reduction at 100 mg

7 peelable blisters
of 4 capsules each

MEKTOVI® (binimetinib) is supplied as 15 mg tablets

Packs of 84 tablets

For patients treated with MEKTOVI® at any dose

7 blisters
of 12 tablets each

MEKTOVI® contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take MEKTOVI®.

Please refer to the Summaries of Product Characteristics

Choosing doses to order in the pharmacy[1,2]

BRAFTOVI (encorafenib) + MEKTOVI (binimetinib)

BRAFTOVI 450 mg | QD

BRAFTOVI 75 mg

1X6 capsules = 1 peelable blister

Daily dosage

4 Weeks
4 packs

MEKTOVI 45 mg | BID

MEKTOVI® 45 mg

2X3 tablets = half blister

Daily dosage

4 Weeks
2 packs

Dose to be taken once a day

BRAFTOVI

			4 Weeks
300 mg	4x	75 mg	2 packs + 4 peelable blisters + 4 capsules
225 mg	3x	75 mg	2 packs
100 mg	2x	50 mg	2 packs

Dose to be taken twice a day

MEKTOVI

			4 Weeks
45 mg	3x	15 mg	2 packs
30 mg	2x	15 mg	1 pack + 2 blisters + 4 tablets

Please refer to the Summaries of Product Characteristics

Choosing doses to order in the pharmacy[1,2]

BRAFTOVI (encorafenib) + MEKTOVI (binimetinib)

BRAFTOVI 450 mg | QD

BRAFTOVI 75 mg

1X6 capsules = 1 peelable blister

Daily dosage

4 Weeks: 4 packs

MEKTOVI 45 mg | BID

MEKTOVI® 45 mg

2X3 tablets = half blister

Daily dosage

4 Weeks: 2 packs

Dose to be taken once a day

BRAFTOVI

300 mg	4x	75 mg	4 Weeks: 3 packs
225 mg	3x	75 mg	4 Weeks: 2 packs
100 mg	2x	50 mg	4 Weeks: 2 packs

Dose to be taken twice a day

MEKTOVI

45 mg	3x	15 mg	4 Weeks: 2 packs
30 mg	2x	15 mg	4 Weeks: 2 packs

Please refer to the Summaries of Product Characteristics