



DOSING & ADMINISTRATION GUIDE



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}



Recommended dose adjustments^{1,2}



Dosage forms and strengths^{1,2}



Choosing doses to order in the pharmacy^{1,2}



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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A risk to the newborns/infants cannot be excluded.



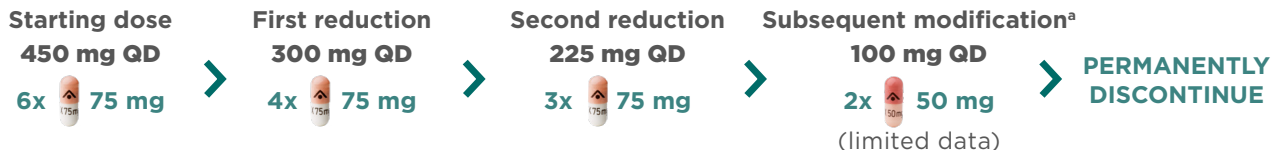
Recommended dose adjustments^{1,2}

BRAFTOVI[®] + **MEKTOVI**[®]
(encorafenib) (binimetinib)

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

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

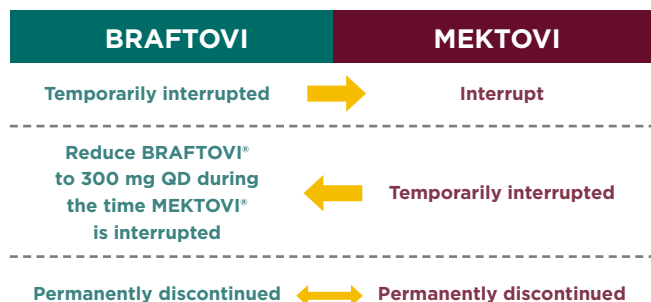
BRAFTOVI[®]
(encorafenib)



MEKTOVI[®]
(binimetinib)



Dose interruption and discontinuation



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[®].

^aThere are limited data for dose reduction to 100 mg QD. If unable to tolerate 100 mg QD, permanently discontinue BRAFTOVI[®].¹

^bIf 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[™] + **MEKTOVI**[™]
(encorafenib) (binimetinib)

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[®].



Choosing doses to order in the pharmacy^{1,2}

BRAFTOVI[™] + **MEKTOVI**[™]
(encorafenib) (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

2 packs
+ **4** peelable
blisters
+ **4** capsules



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

1 pack
+ **2** blisters
+ **4** tablets



Choosing doses to order in the pharmacy^{1,2}

BRAFTOVI[™] + **MEKTOVI**[™]
(encorafenib) (binimetinib)



BRAFTOVI

450 mg | QD

BRAFTOVI[™] **1X6** capsules
75 mg = 1 peelable blister

Daily dosage

4 Weeks

4
packs



MEKTOVI

45 mg | BID

MEKTOVI[®] **2X3** tablets
45 mg = 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