THERAPY MANAGEMENT GUIDE

BRAFTOVI® (encorafenib) + MEKTOVI® (binimetinib)

FOLLOW UP

MONITOR
patients for optimal treatment

MANAGE
adverse reactions with dose modifications

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.

LABORATOIRES Pierre Fabre

MANAGE & MONITOR

A therapy management guide to support your patients receiving

BRAFTOVI® (encorafenib) + MEKTOVI® (binimetinib)

- MONITORING PATIENTS DURING TREATMENT
- SAFETY PROFILE OF THE COMBINATION
- RECOMMENDED DOSE ADJUSTMENTS
- MANAGING ADVERSE REACTION THROUGH DOSE MODIFICATION
- DOSAGE FORMS AND STRENGTHS
- REFERENCES

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RECOMMENDATIONS ON MONITORING PATIENTS DURING TREATMENT[1,2]

Monitoring at treatment initiation* and during treatment helps ensure optimal adverse reaction management and treatment.

		DURING TREATMENT	AFTER TREATMENT
Blood tests	Liver laboratory values	Should be monitored at least monthly during the first 6 months of treatment and then as clinically indicated	
	CK and creatinine levels		
	Serum electrolytes abnormalities (including magnesium and potassium)	Should be corrected during treatment	
Cardiac monitoring	Blood pressure measurements	Should be monitored with control of hypertension by standard therapy as clinically appropriate	
	Echocardiogram/MUGA scan (LVEF)	1 month after initiation and approximately every 3 months thereafter or more frequently if clinically indicated	
	ECG (QT prolongation)		
Ophthalmologic evaluation		Assess at each visit and refer for ophthalmologic exam if new or worsening symptoms are found	
Cutaneous Malignancies assessments	Dermatologic evaluation	Every 2 months	For up to 6 months after treatment discontinuation
Noncutaneous malignancy assessments	Head and neck examination	As clinically appropriate	As clinically appropriate
	Chest/abdomen CT scan		
	Anal and pelvic examinations (for women)		
	Complete blood cell counts		

Specific monitoring might apply if clinically indicated

*For more information about monitoring at treatment initiation please refer to the SmPCs or the start therapy management guide.

CK, creatine kinase; CT, computerised tomography; ECG, electrocardiogram; MUGA, multiple-gated acquisition; LVEF, Left Ventricular Ejection Fraction; QT interval corrected.

Please see the Summaries of Product Characteristics

For Prior treatment:

Please refer to the start therapy management guide

SAFETY PROFILE OF THE COMBINATION[1,2]

Very common	Common	Uncommon
Eye disorders		
Visual impairment[a] RPED[a]	Uveitis[a]	×
Cardiac disorders		
×	LVD[b]	×
Renal and urinary disorders		
×	Renal failure[a]	×
Vascular disorders		
Haemorrhage[d] Hypertension[a]	VTE[e]	×

Very common	Common	Uncommon
Skin and subcutaneous disorders		
Hyperkeratosis[a] Rash[a] Dry skin[a] Pruritus[a] Alopecia[a]	Dermatitis acneiform[a] PPES Erythema[a] Panniculitis[a] Photosensitivity[a]	×
Neoplasms benign, malignant, & unspecified		
×	Basal cell carcinoma[a] Skin papilloma[a] cuSCC[c]	×
Blood and lymphatic system disorders		
Anaemia	×	×
Metabolism disorders		
×	×	Tumour lysis syndrome (frequency not known)

The management of ARs may require dose reduction, temporary interruption, or treatment discontinuation.
For more information please refer to the SmPCs or the treatment follow-up guide.

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[a] Composite terms which included more than one preferred term.
[b] Includes left ventricular dysfunction, ejection fraction decreased, cardiac failure, and ejection fraction abnormal.
[c] Includes keratoacanthoma, squamous cell carcinoma, lip squamous cell carcinoma, and squamous cell carcinoma of the skin.
[d] Includes haemorrhage at various sites including cerebral haemorrhage.
[e] Includes pulmonary embolism, deep vein thrombosis, embolism, thrombophlebitis, superficial thrombophlebitis, and thrombosis.

AR, adverse reaction; cuSCC, cutaneous squamous cell carcinoma; LVD, left ventricular dysfunction; PPES, palmoplantar erythrodysaesthesia syndrome; RPED, retinal pigment epithelial detachment; VTE, venous thromboembolism.

Please see the Summaries of Product Characteristics

SAFETY PROFILE OF THE COMBINATION[1,2]

Investigations

Very common	Common	Uncommon
Blood creatine phosphokinase increased γ-glutamyl transferase increased[a] Transaminase increased[a]	Blood alkalinephosphatase increased Blood creatinine increased[a] Amylase increased Lipase increased	×

Gastrointestinal disorders

Very common	Common	Uncommon
Nausea Vomiting[a] Constipation Abdominal pain[a] Diarrhoea[a]	Colitis[f]	Pancreatitis[a]

Musculoskeletal and connective tissue disorders

Very common	Common	Uncommon
Arthralgia[a] Pain in extremity Back pain Muscular disorders/myalgia[g]	×	Rhabdomyolysis

Immune system disorders

Very common	Common	Uncommon
×	Hypersensitivity[h]	×

Nervous system disorders

Very common	Common	Uncommon
Neuropathy peripheral[a] Dizziness[a] Headache[a]	Dysgeusia[a]	Facial paresis[i]

General disorders and administration site conditions

Very common	Common	Uncommon
Fatigue[a] Pyrexia[a] Peripheral oedema[j]	×	×

The management of ARs may require dose reduction, temporary interruption, or treatment discontinuation.
For more information please refer to the SmPCs or the treatment follow-up guide.

[a] Composite terms which included more than one preferred term.
[f] Includes colitis, ulcerative colitis, enterocolitis, and proctitis.
[g] Includes myalgia, muscular weakness, muscle spasm, muscle injury, myopathy, and myositis.
[h] Includes angioedema, drug hypersensitivity, hypersensitivity, hypersensitivity vasculitis, and urticaria.
[i] Includes facial nerve disorder, facial paralysis, and facial paresis.
[j] Includes fluid retention, peripheral oedema, and localised oedema.

AR, adverse reaction.

Please see the Summaries of Product Characteristics

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RECOMMENDED DOSE ADJUSTMENTS[1,2]

Dose reduction and discontinuation

Dose interruption and discontinuation

BRAFTOVI (encorafenib)

Starting dose	First reduction	Second reduction	Subsequent modification[a,c]	
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 modifications are recommended to manage certain adverse reactions.

Please see the following section — Managing AR through dose modification

BRAFTOVI + MEKTOVI are indicated to be taken in combination. The management of ARs may require dose reduction, temporary interruption, or treatment discontinuation.

[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[2]. [c] For patients with mild hepatic impairment, administration of BRAFTOVI should be undertaken with caution at a reduced dose. In the absence of clinical data, BRAFTOVI is not recommended in patients with moderate to severe hepatic impairment.

AR, adverse reaction; BID, twice daily; QD, once daily.

Please see the Summaries of Product Characteristics

RECOMMENDED DOSE ADJUSTMENTS[1,2]

Dose reduction and discontinuation

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

QD, once daily.

Please see the Summaries of Product Characteristics

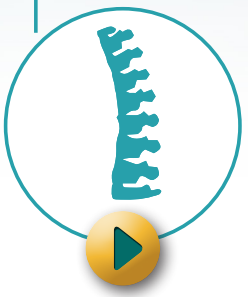
MANAGING AR THROUGH DOSE MODIFICATION

Ocular events

Cardiac

Skin & subcutaneous

Musculoskeletal



Liver laboratory abnormalities & hepatotoxicity

Lung

Vascular

Other[a]

[a] Exceptions where dose modifications are necessary for BRAFTOVI only (adverse reactions primarily related to BRAFTOVI) are: PPES, uveitis including iritis and iridocyclitis, and QTc prolongation. If one of these toxicities occurs, see section 4.2 of the BRAFTOVI Summary of Product Characteristics for dose modification instructions for BRAFTOVI. Exceptions where dose modifications are necessary for MEKTOVI only (adverse reactions primarily related to MEKTOVI) are: retinal pigment epithelial detachment (RPED) and retinal vein occlusion (RVO), interstitial lung disease (ILD)/pneumonitis, cardiac dysfunction, creatine phosphokinase (CK) elevation and rhabdomyolysis, and venous thromboembolism (VTE). If one of these toxicities occurs, see section 4.2 of the MEKTOVI Summary of Product Characteristics for dose modification instructions for MEKTOVI

AR, adverse reaction.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Ocular events

RPED[1,2] → RVO[1,2] → Uveitis including iritis and iridocyclitis[1,2] → AR LIST

	BRAFTOVI	MEKTOVI
GRADE 4 Symptomatic associated with reduced visual acuity (Grade 4)	Permanently discontinue both drugs.	Permanently discontinue both drugs.
GRADE 3 Symptomatic	If MEKTOVI is withheld, the BRAFTOVI 450 mg dose should be **reduced to 300 mg.**	**Withhold for up to 2 weeks and repeat ophthalmologic monitoring including visual acuity assessment.** If improved to Grade 0 or 1: **resume at same dose.** If improved to Grade 2: **resume at a lower dose.** If not improved to Grade 2: **permanently discontinue.**
GRADE 2 Symptomatic		
GRADE 1	×	×

AR, adverse reaction; RPED, retinal pigment epithelial detachment; RVO, retinal vein occlusion.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Occular events

RPED[1,2] | **RVO[1,2]** | Uveitis including iritis and iridocyclitis[1,2] | AR LIST

	BRAFTOVI	MEKTOVI
GRADE 4	Permanently discontinue both drugs.	Permanently discontinue both drugs.
GRADE 3	Permanently discontinue both drugs.	Permanently discontinue both drugs.
GRADE 2	Permanently discontinue both drugs.	Permanently discontinue both drugs.
GRADE 1	Permanently discontinue both drugs.	Permanently discontinue both drugs.

AR, adverse reaction; RPED, retinal pigment epithelial detachment; RVO, retinal vein occlusion.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Ocular events

RPED[1,2] | RVO[1,2] | **Uveitis including iritis and iridocyclitis[1,2]** | AR LIST

	BRAFTOVI	MEKTOVI
GRADE 4	Permanently discontinue both drugs and **follow up with ophthalmologic monitoring.**	Permanently discontinue both drugs and **follow up with ophthalmologic monitoring.**
GRADE 3	**Withhold for Grade 1/2 uveitis that doesn't respond to ocular therapy or for Grade 3 uveitis and monitor within 2 weeks.** - If Grade 1 uveitis improves to Grade 0, then **resume at the same dose.** - If Grade 2 or 3 uveitis improves to Grade 0 or 1, then **resume at a reduced dose.** **If not improved within 6 weeks, permanently discontinue** and follow up with ophtalmologic monitoring.	If BRAFTOVI is withheld, MEKTOVI should be withheld.
GRADE 2		
GRADE 1		

AR, adverse reaction; RPED, retinal pigment epithelial detachment; RVO, retinal vein occlusion.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Cardiac

LVEF[1,2] → QTc prolongation[1,2] → AR LIST

	BRAFTOVI	MEKTOVI
GRADE 4[b]	Permanently discontinue both drugs. LVEF should be **evaluated every 2 weeks** until recovery.	Permanently discontinue both drugs. LVEF should be **evaluated every 2 weeks** until recovery.
GRADE 3[b]		
GRADE 2[a]	If MEKTOVI is withheld, the BRAFTOVI 450 mg dose should be **reduced to 300 mg.**	Withhold and evaluate LVEF **every 2 weeks. Resume at a reduced dose** if both of the following are present within 4 weeks: - LVEF is ≥ LLN. - Absolute decrease from baseline is ≤10%. **If LVEF does not recover within 4 weeks, permanently discontinue.**
GRADE 1	×	×

[a] Grade 2 LVEF decrease or asymptomatic, absolute decrease in LVEF of greater than 10% from baseline that is below LLN. [b] Grade 3 or 4 LVEF decrease or symptomatic LVD.

AR, adverse reaction; LLN, lower limit of normal; LVD, left ventricular dysfunction; LVEF, left ventricular ejection fraction; QTc, QT interval corrected.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Cardiac

LVEF[1,2] | **QTc prolongation[1,2]** | AR LIST

	BRAFTOVI	MEKTOVI
QTcF >500 ms & **increased by > 60 ms** from pre-treatment value	Permanently discontinue both drugs.	Permanently discontinue both drugs.
QTcF >500 ms & **change ≤ 60 ms** from pre-treatment value	**Withhold and monitor risk factors.** - When QTcF returns to ≤ 500 ms, resume at a reduced dose. - If more than 1 recurrence, discontinue.	If BRAFTOVI is withheld, MEKTOVI should be withheld.

AR, adverse reaction; LVEF, left ventricular ejection fraction; QTc, QT interval corrected; QTcF, QT interval corrected by Fridericia's formula.
If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.
Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Skin and subcutaneous

Cutaneous reactions[1,2] → **PPES**[1,2] → **AR LIST**

	BRAFTOVI	MEKTOVI
GRADE 4	Permanently discontinue both drugs.	Permanently discontinue both drugs.
GRADE 3	Withhold both drugs **until improved to Grade 0 or 1.** - If first occurrence, **resume at same dose.** - If recurrent Grade 3, **resume at a reduced dose.**	Withhold both drugs **until improved to Grade 0 or 1.** - If first occurrence, **resume at same dose.** - If recurrent Grade 3, **resume at a reduced dose.**
GRADE 2	Maintain dose **If rash worsens or does not improve within 2 weeks with treatment, withhold until Grade 0 or 1 and then resume at same dose.**	Maintain dose **If rash worsens or does not improve within 2 weeks with treatment, withhold until Grade 0 or 1 and then resume at same dose if first occurrence or reduced dose if recurrent Grade 2.**
GRADE 1	×	×

AR, adverse reaction; PPES, palmoplantar erythrodysaesthesia syndrome.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Skin and subcutaneous

Cutaneous reactions[1,2] → PPES[1,2] → AR LIST

	BRAFTOVI	MEKTOVI
GRADE 4	×	×
GRADE 3	Withhold, **institute supportive measures** such as topical therapy, and reassess weekly. - When improved to Grade 0 or 1, **resume at same dose level or a reduced dose.**	If BRAFTOVI is withheld, MEKTOVI should be withheld.
GRADE 2	Maintain dose and **institute supportive measures** such as topical therapy. - **If not improved within 2 weeks, withhold until improved to Grade 0 or 1, then resume at same dose or a reduced dose.**	
GRADE 1	×	×

AR, adverse reaction; PPES, palmoplantar erythrodysaesthesia syndrome.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Musculoskeletal

Asymptomatic rhabdomyolysis or CK elevations[1,2] → **Symptomatic rhabdomyolysis or CK elevations[1,2]** → AR LIST

		BRAFTOVI	MEKTOVI
GRADE 4	CK > 10 x ULN asymptomatic	If MEKTOVI is withheld, the BRAFTOVI 450 mg dose should be **reduced to 300 mg.**	Withhold until improved to Grade 0 or 1 and **ensure patient is adequately hydrated.**
GRADE 3	CK > 5-10 x ULN asymptomatic	Maintain dose.	Maintain dose and **ensure patient is adequately hydrated.**
GRADE 2	×	×	×
GRADE 1	×	×	×

AR, adverse reaction; CK, creatine kinase; ULN, upper limit of normal.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Musculoskeletal

Asymptomatic rhabdomyolysis or CK elevations[1,2]

Symptomatic rhabdomyolysis or CK elevations[1,2]

AR LIST

		BRAFTOVI	MEKTOVI
GRADE 4	Grade 4 (CK > 5 x ULN) with muscle symptoms OR with renal impairment	If MEKTOVI is withheld, the BRAFTOVI 450 mg dose should be **reduced to 300 mg.**	Withhold until improved to Grade 0 or 1 If resolved in ≤ 4 weeks, resume at a reduced dose. OR permanently discontinue both drugs.
GRADE 3	Grade 3 (CK > 5 x ULN) with muscle symptoms OR with renal impairment		
GRADE 2	×	×	×
GRADE 1	×	×	×

AR, adverse reaction; CK, creatine kinase; ULN, upper limit of normal.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Liver laboratory abnormalities and hepatotoxicity

AST or ALT elevations[1,2]

AR LIST

		BRAFTOVI	MEKTOVI
GRADE 4	First occurrence or recurrent Grade 4 (AST or ALT > 20 x ULN)	Other[1,2]	Other[1,2]
GRADE 3	First occurrence or recurrent Grade 3 (AST or ALT > 5 x ULN and blood bilirubin > 2 x ULN)		
GRADE 2	AST or ALT > 3 x - ≤ 5 x ULN	Maintain dose. **If no improvement within 4 weeks, withhold until improved to Grade 0 or 1 or to pre-treatment/ baseline levels and then resume at the same dose[a].**	Maintain dose. **If no improvement within 2 weeks, withhold until improved to Grade 0 or 1 or to pre-treatment baseline levels and then resume at the same dose[a].**
GRADE 1	×	×	×

[a] When MEKTOVI is withheld, the 450 mg BRAFTOVI dose should be reduced to 300 mg.[1,2]

ALT, alanine aminotransferase; AR, adverse reaction; AST, aspartate transaminase; ULN, upper limit of normal.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Lung

ILD/pneumonitis[1,2]

AR LIST

	BRAFTOVI	MEKTOVI
GRADE 4	Permanently discontinue both drugs.	Permanently discontinue both drugs.
GRADE 3		
GRADE 2	If MEKTOVI is withheld, the BRAFTOVI 450 mg dose should be **reduced to 300 mg.** If MEKTOVI is permanently discontinued, BRAFTOVI must be permanently discontinued.	**Withhold for up to 4 weeks** - **If improved to Grade 0 or 1, resume at reduced dose.** - **If not resolved within 4 weeks, permanently discontinue.**
GRADE 1	×	×

AR, adverse reaction; ILD, interstitial lung disease.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Vascular

VTE[1,2]

AR LIST

		BRAFTOVI	MEKTOVI
GRADE 4	Grade 4 PE	Permanently discontinue both drugs.	Permanently discontinue both drugs.
GRADE 3	Uncomplicated DVT or PE ≤ Grade 3	If MEKTOVI is withheld, the BRAFTOVI 450 mg dose should be **reduced to 300 mg.**	**Withhold** - **If improved to Grade 0 or 1, resume at a reduced dose.** - **If not improved, permanently discontinue.**

AR, adverse reaction; DVT, deep vein thrombosis; PE, pulmonary embolism; VTE, venous thromboembolism.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

MANAGING AR THROUGH DOSE MODIFICATION

Dose modification | Other[a]

Other[a,1,2] AR LIST

		BRAFTOVI	MEKTOVI
GRADE 4	Recurrent Grade 4 ARs	Permanently discontinue both drugs.	Permanently discontinue both drugs.
	First occurrence of any Grade 4 AR	Withhold both drugs for **up to 4 weeks:** • **If improved to Grade 0 or 1 or to pre-treatment/ baseline levels, then resume at a reduced dose.** • If no improvement, permanently discontinue both drugs OR permanently discontinue both drugs.	Withhold both drugs for **up to 4 weeks:** • **If improved to Grade 0 or 1 or to pre-treatment/ baseline levels, then resume at a reduced dose.** • If no improvement, permanently discontinue both drugs OR permanently discontinue both drugs.
GRADE 3	Recurrent Grade 3 ARs	Consider permanently discontinuing both drugs.	Consider permanently discontinuing both drugs.
	First occurrence of any Grade 3 AR	Withhold both drugs for **up to 4 weeks.** **If improved to Grade 0 or 1 or to pre-treatment/ baseline levels, resume at a reduced dose.** If not improved, permanently discontinue both drugs.	Withhold both drugs for **up to 4 weeks.** **If improved to Grade 0 or 1 or to pre-treatment/ baseline levels, resume at a reduced dose.** If not improved, permanently discontinue both drugs.
GRADE 2	Recurrent or intolerable Grade 2 ARs		
GRADE 1			

[a] Exceptions where dose modifications are necessary for BRAFTOVI only (adverse reactions primarily related to BRAFTOVI) are: PPES, uveitis including iritis and iridocyclitis, and QTc prolongation. If one of these toxicities occurs, see section 4.2 of the BRAFTOVI Summary of Product Characteristics for dose modification instructions for BRAFTOVI. Exceptions where dose modifications are necessary for MEKTOVI only (adverse reactions primarily related to MEKTOVI) are: retinal pigment epithelial detachment (RPED) and retinal vein occlusion (RVO), interstitial lung disease (ILD)/pneumonitis, cardiac dysfunction, creatine phosphokinase (CK) elevation and rhabdomyolysis, and venous thromboembolism (VTE). If one of these toxicities occurs, see section 4.2 of the MEKTOVI Summary of Product Characteristics for dose modification instructions for MEKTOVI.

If MEKTOVI is permanently discontinued, BRAFTOVI should be discontinued. If BRAFTOVI is permanently discontinued, MEKTOVI should be discontinued.

Please see the Summaries of Product Characteristics

AR, adverse reaction; PPES, palmoplantar erythrodysaesthesia syndrome; QTc, QT interval corrected.

BRAFTOVI + MEKTOVI IS AVAILABLE IN SEVERAL DOSAGE FORMS AND STRENGTHS[1,2]

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

BRAFTOVI® 75 mg is available in packs of 42x1 capsules (7 peelable blisters of 6 capsules each) for patients treated at full dose or undergoing dose reduction at 300 mg and 225 mg.

BRAFTOVI® 50 mg is available in packs of 28x1 capsules (7 peelable blisters of 4 capsules each) for patients undergoing dose reduction at 100 mg.

MEKTOVI (binimetinib) is supplied as 15 mg tablets

MEKTOVI® is available in packs of 84 tablets (7 blisters of 12 tablets each) for patients treated with MEKTOVI® at any dose.MEKTOVI® contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take MEKTOVI®.

REFERENCES

1. BRAFTOVI Summary of Product Characteristics. Pierre Fabre Médicament, 2024.
2. MEKTOVI Summary of Product Characteristics. Pierre Fabre Médicament, 2024.

Also available

A guide to optimize your patients **treatment initiation** with BRAFTOVI + MEKTOVI

Contact your local Pierre Fabre representative for more information

LABORATOIRES Pierre Fabre

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