אפריל 2025

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

שלום רב,

הנדון: עדכוני בטיחות בעלוני התכשיר -
Tafinlar 50 mg, 75 mg, Hard capsules

חברת נוברטיס ישראל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשירים:
Tafinlar 50 mg & Tafinlar 75 mg

התוויות התכשיר:

Melanoma
Dabrafenib as monotherapy or in combination with trametinib is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.
Adjuvant treatment of melanoma
Dabrafenib in combination with trametinib is indicated for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection.
Non-small cell lung cancer (NSCLC)
Dabrafenib in combination with trametinib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation.
Anaplastic Thyroid Cancer (ATC)
Dabrafenib is indicated, in combination with trametinib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.
BRAF V600E Mutation-Positive Unresectable or Metastatic Solid Tumors
Dabrafenib is indicated, in combination with trametinib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.
Limitations of use: Dabrafenib is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition.
BRAF V600E Mutation-Positive Low-Grade Glioma
Dabrafenib is indicated, in combination with trametinib, for the treatment of pediatric patients 6 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

חומר פעיל: DABRAFENIB (AS MESILATE) 50mg, 75mg

בהודעה זו מפורטים העדכונים המהווים עדכונים מהותיים בלבד. למידע מלא יש לעיין בעלוני התכשיר.
(טקסט שנוסף מסומן עם קו תחתי ושינויים אשר מהווים מידע בטיחות חדש מסומנים ברקע צהוב)

העלונים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על-ידי פניה לבעל הרישום:
נוברטיס ישראל בע"מ. תוצרת הארץ 6, ת.ד. 7126, תל אביב

בברכה,

ניב טובי
רוקח ממונה

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P.O.Box 7126 6 Tozeret Haaretz street, Tel Aviv
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4.4 Special warnings and precautions for use

[…]

Visual impairment

In clinical trials ophthalmologic reactions, including uveitis, iridocyclitis and iritis, have been reported in patients treated with dabrafenib as monotherapy and in combination with trametinib. Patients should be routinely monitored for visual signs and symptoms (such as change in vision, photophobia and eye pain) while on therapy.

No dose modifications are required as long as effective local therapies can control ocular inflammation. If uveitis does not respond to local ocular therapy, withhold dabrafenib until resolution of ocular inflammation and then restart dabrafenib reduced by one dose level. No dose modification of trametinib is required when taken in combination with dabrafenib following diagnosis of uveitis.

Cases of biocular panuveitis or biocular iridocyclitis suggestive of Vogt-Koyanagi-Harada syndrome have been reported in patients treated with dabrafenib in combination with trametinib. Withhold dabrafenib until resolution of ocular inflammation and consider consulting an ophthalmologist. Systemic corticosteroid treatment may be necessary.

RPED and RVO may occur with dabrafenib in combination with trametinib. Please refer to the trametinib Prescribing Information (see section 4.4). No dose modification of dabrafenib is required when taken in combination with trametinib following diagnosis of RVO or RPED.

4.8 Undesirable effects

[…]

Table 6. Adverse reactions with dabrafenib in combination with trametinib

System organ class	Frequency (all grades)	Adverse reactions
[…]		
Eye disorders	Common	Vision blurred
		Visual impairment
		Uveitis[e]
	Uncommon	Chorioretinopathy
		Retinal detachment
		Periorbital oedema

[…]

[e] Includes cases of biocular panuveitis or biocular iridocyclitis suggestive of Vogt-Koyanagi-Harada syndrome

[…]

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