פברואר 2020

רופא/ה נכבד/ה
רוקח/ת נכבד/ה שלום רב,

<u>פרסום עדכון בעלון התכשיר :</u>
<u>TAGRISSO 40mg film-coated tablets</u>
<u>TAGRISSO 80mg film-coated tablets</u>

הרכב:

TAGRISSO 40 mg tablets
Each tablet contains osimertinib 40mg (equivalent to 47.7mg of osimertinib mesylate)

TAGRISSO 80 mg tablets
Each tablet contains osimertinib 80mg (equivalent to 95.4mg of osimertinib mesylate)

התוויה:

Tagrisso as monotherapy is indicated for:

- the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations.
- the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.

חברת אסטרהזניקה ישראל מבקשת להודיע על עדכון עלון בהתאם להוראות משרד הבריאות בתאריך **אוגוסט 2019.**

העדכון העיקרי בעלון לרופא הוא:

4.2 Posology and method of administration

<u>Hepatic impairment</u>

<u>Based on clinical studies, no dose adjustments are necessary in patients with mild hepatic impairment (Child Pugh A) or moderate hepatic impairment (Child Pugh B). Similarly, based on population pharmacokinetic analysis,</u> no dose adjustment is recommended in patients with mild hepatic impairment (total bilirubin <u><</u><upper limit of normal (ULN) and aspartate aminotransferase (AST) > ULN or total bilirubin ~~between~~>1.0 to 1.5x ULN ~~or total bilirubin between 1.0 to 1.5xULN~~ and any AST) or moderate hepatic impairment (total bilirubin between 1.5 to 3 times ULN and any AST).~~but caution should be used when administering TAGRISSO to these patients.~~ The safety and efficacy of

this medicinal product has not been established in patients with severe hepatic impairment. Until additional data become available, use in patients with ~~moderate or~~ severe hepatic impairment is not recommended (see section 5.2).

4.8 Undesirable effects

Table 2. Adverse drug reactions reported in FLAURA and AURA studies[a]

MedDRA SOC	MedDRA term	CIOMS descriptor/ overall frequency (allCTCAE grades) [b]	Frequency of CTCAE grade 3 or higher
Skin and subcutaneous tissue disorders	Rash[f]	Very common (47%)	0.9%
	Dry skin[g]	Very common (33%)	0.1%
	Paronychia[h]	Very common (31%)	0.3%
	Pruritus[i]	Very common (17%)	0.1%
	Stevens-Johnson syndrome[j]	Rare (0.02%)	

[h]Includes cases reported within the clustered terms: Nail bed disorder, nail bed inflammation, nail bed infection, nail discoloration, nail pigmentation, nail disorder, nail toxicity, nail dystrophy, nail infection, nail ridging, onychalgia, onychoclasis, onycholysis, onychomadesis, onychomalacia, paronychia.

לא היה עדכון בעלון לצרכן.

העלונים מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בכבוד רב,

אורה סטוליק
רוקחת ממונה
אסטרהזניקה (ישראל) בע"מ

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