

Safety Alert

Jun 2024

Osimertinib – Risk of Hyperpigmentation

EDA performs label update to include the following:

Undesirable effects

Tabulated list of adverse reactions

<i>MedDRA SOC</i>	<i>MedDRA term</i>	<i>CIOMS descriptor/ overall frequency (all CTCAE grades)</i>	<i>Frequency of CTCAE grade 3 or higher</i>
<i>Skin and subcutaneous tissue disorders</i>	<i>Skin hyperpigmentation</i>	<i>Uncommon (0.8%)</i>	<i>0</i>

Background:

Therapeutic Indication

Osimertinib as monotherapy is indicated for:

- the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIa non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations
- the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations.

References:

TGA ([Click here](#))