

ספטמבר 2017

רופא/ה נכבד/ה  
רוקח/ת נכבד/ה שלום רב,

**Iressa 250 mg Film-Coated Tablets : פרסום עדכון בעלון התכשיר :**

**הרכב:**

Each tablet contains 250 mg of gefitinib

**התוויה:**

IRESSA is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK.

**התווית נגד:**

Hypersensitivity to the active substance or to any of the excipients.  
Breast-feeding.

**העלון עודכן באוגוסט 2017, המידע העדכני הוא בסעיפים הבאים:**

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Excipient with known effect....

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

IRESSA is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK (see section 4.4).

**4.7 Effects on ability to drive and use machines**

During treatment with gefitinib....

**4.8 Undesirable effects**

**Table 1 Adverse reactions**

Skin and subcutaneous tissue disorders	Common	Allergic reactions (1.1%)(including angioedema and urticaria
Hepatobiliary disorders	Uncommon	Hepatitis **
General disorders and administration site conditions	...	....

\*\*This includes isolated reports of hepatic failure which in some cases led to fatal outcomes.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

#### Mechanism of action and pharmacodynamic effects

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#### *Resistance*

Most NSCLC tumours with sensitising EGFR kinase mutations eventually develop resistance to IRESSA treatment, with a median time to disease progression of 1 year. In about 60% of cases, resistance is associated with a secondary T790M mutation for which T790M targeted EGFR TKIs may be considered as a next line treatment option. Other potential mechanisms of resistance that have been reported following treatment with EGFR signal blocking agents include: bypass signalling such as HER2 and MET gene amplification and PIK3CA mutations. Phenotypic switch to small cell lung cancer has also been reported in 5-10% of cases.

**Table 3 Efficacy outcomes for gefitinib versus carboplatin/paclitaxel from the IPASS study**

Population	N	Objective response Rates (ORR) and 95% CI For difference Between treatments <sup>a</sup>	Primary endpoint Progression free survival (PSF) <sup>a,b</sup>	Overall survival <sup>a,b</sup>
Overall	1217	43.0% vs 32.2% [5.3%, 16.1%]	HR 0.74 [0.65, 0.85] 5.7 m vs 5.8 m p<0.0001	HR 0.90 [0.79,1.02] 18.8 m vs 17.4m p=0.1087

### 5.2 Pharmacokinetic properties

Biotransformation

*In vitro* data....

### 5.3 Preclinical safety data

...interval). Clinical experience has not shown a causal association between QT prolongation and gefitinib.

### **6.3 Shelf life**

4 years.

### **6.4 Special precautions for storage**

Store in the original package in order to protect from moisture.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בכבוד רב,

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