

IFO-CELL 2 G
IFO-CELL 5 G

חברת אמ.בי.איי פארמה בע"מ מבקשת להודיע על עדכון בעלון לרופא של התכשיר שבנדון.

התוויות התכשיר:

Testicular tumour

For combination chemotherapy in patients with advanced stage II to IV tumours according to the TNM classification (seminomas and non-seminomas), which do not respond or adequately respond to initial chemotherapy.

Cervical cancer

Palliative cisplatin/ifosfamide combination chemotherapy (without any other combination partners) of cervical carcinoma, FIGO stage IV B (when curative therapy of the disease is not possible with surgery or radiotherapy) – as an alternative to palliative radiotherapy.

Breast cancer

For palliative therapy in advanced, therapy-refractory or recurrent breast cancer.

Non-small-cell lung cancer

For mono- or combination chemotherapy of patients with inoperable or metastatic tumours.

Small-cell lung cancer

For combination chemotherapy.

Soft-tissue sarcoma (incl. osteosarcoma and rhabdomyosarcoma)

For mono- or combination chemotherapy of rhabdomyosarcoma or osteosarcoma after failure of standard therapies. For mono- or combination chemotherapy of other soft-tissue sarcomas after failure of surgery and radiation therapy.

Ewing's sarcoma

For combination chemotherapy after failure of primary cytostatic therapy.

Non-Hodgkin's lymphoma

For combination chemotherapy in patients with highly malignant non-Hodgkin's lymphoma which does not respond, or only insufficiently responds, to the initial therapy. For combination therapy of patients with recurrent tumours.

Hodgkin's lymphoma

For the treatment of patients with primary progressive forms and early relapse of Hodgkin's lymphoma (duration of complete remission shorter than one year) after failure of primary chemotherapeutic or radio-chemotherapeutic treatment – as part of a recognised combination chemotherapy regimen, such as the MINE protocol.

מרכיב פעיל וצורת מינון:

Ifo-Cell 2g

IFOSFAMIDE 2 G / 50 ML Solution for infusion

Ifo-Cell 5g

IFOSFAMIDE 5 G / 25 ML Concentrate for solution for infusion

שינוי בעלון לרופא בוצע בחיי המדף של התכשיר לאחר מיהול.
להלן השינוי שבוצע, מסומן באדום:

6.3 Shelf life

The expiry date is indicated on the printing materials.

~~IFO-cell prepared for use with 0.9% sodium chloride solution or 5% glucose solution, is chemically and physically stable for 4 days when stored in a refrigerator (between 2°C and 8°C) and at room-temperature.~~

Chemical and physical stability of IFO-cell, prepared for use with 5% glucose solution or 0.9% sodium chloride solution has been demonstrated for both 2 days at 25 °C and for 2 days at 2 °C to 8 °C, each followed by one additional day at 25°C.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות:

<https://data.health.gov.il/drugs/index.html#!/byDrug>

ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת אמ.בי.איי פארמה, ת.ד. 5061, קדימה, טל. 09-7719003

בברכה,

גלי קיסר
רוקחת ממונה