



ינואר 2023

רופא/ה רוקח/ת נכבד/ה,

חברת אי ג'י אל מדיקל מבקשת ליידע אתכם על עדכון העלון לרופא של התכשיר:

Hexvix 85 mg

חומר פעיל: Hexaminolevulinate (as hydrochloride) 85 mg

צורת מינון: **Powder and Solvent for intravesical solution**

ההתוויה המאושרת לתכשיר בישראל:

This medicinal product is for diagnostic use only. Hexvix blue light fluorescence cystoscopy is indicated as adjunct to standard white light cystoscopy to contribute to the diagnosis and management of bladder cancer in patients with known or high suspicion of bladder cancer.

בהודעה זו מצוינים השינויים המהותיים בהתאם לעלון האסמכתא. קיימים שינויים מינוריים נוספים. השינויים מסומנים בעלון המצורף. הטקסט המסומן באדום הוסף לעלון, ואילו הטקסט המסומן בקו חוצה נגרע ממנו.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://israeldrugs.health.gov.il/#!/byDrug>

בברכה,
מחלקת רישום
IGL Medical Ltd.

4.8 Undesirable effects

Most of the reported adverse reactions were transient and mild or moderate in intensity. The most frequently reported adverse reactions from clinical studies were bladder spasm, reported by 2.402.0% of the patients, dysuria by 1.81.6%, bladder pain by 1.71.4% and haematuria by 1.71.5%, of the patients. The adverse reactions that were observed were expected, based on previous experience with standard cystoscopy and transurethral resection of the bladder (TURB) procedures

The table below includes adverse reactions from clinical trials and spontaneous reporting. The adverse reactions are classified by System Organ Class and frequency, using the following convention: Very common (>1/10), Common (>1/100 to < 1/10), Uncommon

(> 1/1,000 to < 1/100), Rare (> 1/10,000 to < 1/1,000), Very rare (< 1/10,000), Not known (cannot be estimated from the available data).

System Organ Class (MedDRA)	Frequency	Adverse reaction
Infections and infestations	Uncommon	Cystitis, sepsis, urinary tract infection
Blood and lymphatic system disorders	Uncommon	White blood cell count increased, anaemia
Immune system disorders	Not known	Anaphylactoid shock
Metabolism and nutrition disorders	Uncommon	Gout
Psychiatric disorders	Uncommon	Insomnia
Nervous system disorders	Common Uncommon	Headache
Gastrointestinal disorders	Common	Nausea, vomiting, constipation, diarrhoea
Hepatobiliary disorders	Uncommon	Increased serum bilirubin, hepatic enzyme increased
Skin and subcutaneous tissue disorders	Common Uncommon	Rash, <u>pruritus</u>
Musculoskeletal and connective tissue disorders	Uncommon	Back pain
Renal and urinary bladder disorders	Common	Bladder spasm, bladder pain, dysuria, urinary retention, haematuria
	Uncommon	Urethral pain, pollakuria, micturition urgency, urinary tract disorder
Reproductive system and breast disorders	Uncommon	Balanitis
General disorders and administration site conditions	Common	Pyrexia
Injury, poisoning and procedural complications	Common	Post procedural pain
	Uncommon	Post-operative fever

5.1 Pharmacodynamic properties

[...]

Clinical studies using Hexvix included ~~1072-1174~~ evaluable patients with known bladder cancer, ~~or~~ high suspicion of bladder cancer, or in surveillance of bladder cancer, who underwent white light, followed by blue light cystoscopy, and biopsies.

[...]

A prospective, within patient controlled study showed that blue light flexible cystoscopy with hexaminolevulinate improves detection of tumours compared to white light flexible cystoscopy. Patients with bladder cancer in follow up for tumour recurrence underwent a surveillance examination with white light and blue light flexible cystoscopy. 21% (13/63) of patients had histologically confirmed malignancy detected only with blue light flexible cystoscopy and not by white light examination. 46% (6/13) of patients recurred with high grade pTa or CIS.

[...]

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il>