

BLEOMYCIN PFI

הרכב:

BLEOMYCIN SULFATE 15000 IU/VIAL

ההתוויה הרשומה לתכשיר בישראל:

Bleomycin is useful in the management of the following neoplasms:

Squamous cell carcinoma affecting the mouth, nasopharynx and paranasal sinuses, larynx, oesophagus, cervix, vagina, penis and skin.

Well differentiated tumors usually respond better than anaplastic ones.

Hodgkin's disease and other malignant lymphomas, including mycosis fungoides.

Testicular carcinoma (seminoma and non-seminoma).

Malignant effusions of serous cavities (intrapleural and intraperitoneal).

Secondary indications in which bleomycin has been shown to be of some value include metastatic malignant

melanoma, carcinoma of the thyroid lung and bladder.

Local treatment of refractory warts.

Bleomycin can be used as a single agent, but is generally used in combination with other cytotoxics and/or with radiation therapy.

בהודעה זו כלולים השינויים המהותיים בלבד. בעלונים ישנם שינויים נוספים.
טקסט חדש מסומן עם קו תחתון, טקסט המהווה החמרה **מודגש בצהוב**.

להלן העדכונים העיקריים בעלון לרופא:

4.3 Contraindication

[...]

Bleomycin is contraindicated during breast-feeding (see section 4.6).

4.4 Special warnings and special precautions for use

[...]

A particularly strict benefit/risk assessment is required after pulmonary or mediastinal radiotherapy. In case of renal impairment, bleomycin should only be used with particular caution and at a reduced dose.

[...]

4.5 Interactions with other medicinal products and other forms of interaction

[...]

Careful case-specific assessment of the risks and benefits is required before any planned concomitant or sequential use of other agents or treatments that may increase the likelihood or severity of toxicity (as a result of pharmacodynamic or pharmacokinetic interactions). Patients treated with such combinations must be closely monitored for signs of toxicity to allow for early intervention.

[...]

Combination therapy with cisplatin in particular increases the pulmonary toxicity of bleomycin. Particular caution is therefore required with this combination. Data from the literature suggest that cisplatin should be administered after bleomycin.

[...]

The bacteriostatic efficacy of gentamycin, amikacin and ticarcillin may be reduced.

Administration of live vaccines may result in severe to life-threatening infections in patients whose immune systems are compromised by chemotherapeutic agents, including bleomycin. Vaccination with live vaccines should be avoided in patients receiving bleomycin.

4.8 Undesirable effects

[...]

Blood and lymphatic system disorders

Uncommon: Myelosuppression, Bleeding [...]

[...]

Nervous system disorders:

Common: Headache

Uncommon: Dizziness[...]

[...]

Gastrointestinal disorders

Common: [...] Mucositis [...]

[...]

Hepatobiliary disorders

Rare: Hepatic impairment, Hepatitis

Skin and subcutaneous tissue disorders:

Common: [...] Urticaria [...]

Uncommon: [...] Blister formation over pressure points

[...]

Renal and urinary disorders:

Uncommon: Oliguria, Painful urination, Polyuria, Urinary retention

[...]

General disorders and administration site conditions:

Common: [...] Malaise [...]

Uncommon: [...] Vein wall hypertrophy and venous access stenosis (with IV administration) [...]

[...]

6.3 Shelf life

[...]

Shelf life after reconstitution: 24 hours at 25°C Compatible with: Physiological saline

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

בברכה,
דיויד וגנר
רוקח ממונה
מגאפארם בע"מ