Bleomycin 15000 IU Powder for solution for injection/ infusion

Version 3 Last updated on 11-Jun-2021
Product ID 20000/0001
Active ingredient Bleomycin
Licence holder Accord Healthcare Limited

Legal Category
PBR Prescribing information

SmPC Patient Leaflet

This reference is intended for use by health professionals

1. Name of the medicinal product
Bleomycin 15000 IU Powder for solution for injection/ infusion
2. Qualitative and quantitative composition
Each vial contains bleomycin sulfate (of a bleomycin sac fermentation system)
Excipient with known effect
Sodium (as part of the buffer system)
For the full list of excipients, see section 6.1.
3. Pharmaceutical form
Powder for solution for injection/infusion
White to off white lyophilisate or powder
4. Clinical particulars
Cytotoxic: 28 to 100 vials/week
4.1. Therapeutic indications
4.2. Posology and method of administration
4.3. Contraindications
4.4. Special warnings and precautions for use
4.5. Interaction with other medicinal products and other forms of interaction
4.6. Fertility, pregnancy and lactation
4.7. Effects on ability to drive and use machines
4.8. Undesirable effects
4.9. Overdose
5. Pharmacological properties
5.1. Pharmacodynamic properties
5.2. Pharmacokinetic properties
5.3. Preclinical safety data
6. Pharmaceutical particulars
6.1. List of excipients
6.2. Incompatibilities
6.3. Shelf life
6.4. Special precautions for storage
6.5. Nature and contents of container
6.6. Special precautions for disposal and other handling
7. Marketing authorisation holder
8. Marketing authorisation number(s)
9. Date of first authorisation/renewal of the authorisation
10. Date of revision of the text

Company contact details

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4. Clinical particulars

Cytotoxic: 28 to 100 vials/week

4.1. Therapeutic indications

Bleomycin can be used in the treatment of:

- Squamous cell carcinoma (SCC) of the head and neck, cervix and external genitalia
- Testicular seminoma
- Non-Hodgkin's lymphoma (in combination with other cytotoxic agents)
- Testicular seminoma (seminoma and non-seminoma)
- Hodgkin's lymphoma (in hodgkin's lymphoma bleomycin should be used in combination with other cytotoxic agents)

Bleomycin can be used as a chemotherapy as well as a palliative treatment (with concomitant palliative radiation therapy).

4.2. Posology and method of administration

Posology

Bleomycin therapy is by intravenous, intramuscular or subcutaneous injection. Bleomycin should be administered twice a week (day1 and day4) or once a week. The dose should be 15 mg/day and not to exceed 150 mg/week. Bleomycin should be given with caution to patients with renal impairment (see section 4.4).

Please refer to the product information for the other medicinal products to be used in combination with bleomycin.

Please refer to the product information for the other medicinal products to be used in combination with bleomycin. Bleomycin should not be used when the clinical supervision of a physician specialised in the use of cytotoxic medical products is not available. Bleomycin should be used with caution in the elderly.

Bleomycin may be administered intravenously, intramuscularly, subcutaneously or intraperitoneally. Intralesional injection should only be the tumour may occasionally be indicated.

Adults

Dose:

1) Squamous cell carcinoma:

Intravenous administration of 10-15 IU/m² (4-6 IU/m² body surface area (BSA), once or twice a week, or intervals of 1-3 weeks) as a lifetime cumulative dose of 400 IU/m² (160 IU/m² BSA).

Intramuscular injection of 10 IU/m² (4 IU/m² BSA) once or twice a week or in 1-2 consecutive days, at intervals of 3-4 weeks.

2) Testicular seminoma:

Where germ cells are highly chemosensitive administration of 30 IU/m² (12 IU/m² BSA), once a week, for a cumulative dose of 300 IU/m² (120 IU/m² BSA). The decrease of the quantity of administered bleomycin, to prevent pulmonary toxicity should be treated with caution. Bleomycin should be given by intravenous injection, usually as part of a combination therapy. Bleomycin should be given by intravenous injection, the total dose is known as the bolus.

3) Testicular tumours

Where germ cells are highly chemosensitive administration of 30 IU/m² (12 IU/m² BSA), once a week, or intervals of 3-4 weeks up to a total cumulative dose of 300 IU/m² (120 IU/m² BSA).

The intravenous infusion of the dose of 15 IU/m² (6 IU/m² BSA) is performed for 5-24 hours in 0.9 mililitre/ml of saline, or 5 % dextrose solution.

4) Malignant pleural effusion

20 U IT, 120 IU/m² (48 IU/m² BSA) bleomycin sulfate, monodose, as a single dose, which can be repeated after 3-4 weeks. Intracavitary administration of bleomycin is performed after the drainage of the effusion, when the lung is fully expanded. Bleomycin should be injected into the pleural cavity, using a trocar and a long needle.

The development of pneumonitis is the most serious problem in the administration of intrakavitary bleomycin with respect to the treatment of malignant pleural effusion. Pneumonitis occurs in 2-3 % of the treated patients. Pleurodesis with bleomycin is not recommended because of the risk of pneumonitis. Bleomycin should be used with caution in patients with impaired pulmonary function.

In cases of hypercalcemia associated with bleomycin tumours, intravenous injection quickly and can be observed within two hours. If the response is not satisfactory, the dose can be increased to 30 IU/m² (12 IU/m² BSA) administered twice a week, or intervals of 3-4 weeks. Bleomycin can be given as a three-weekly dose of intravenous or subcutaneous.

Elderly population (from the age 70):

Because of the risk of pulmonary toxicity, bleomycin should be reduced according to the following table:

Age	Dose
70 and under	150 x 10³ IU
71-75	100 x 10³ IU
80-85	200 x 10³ IU
85 and over	100 x 10³ IU

Paediatric population

Bleomycin should be used with caution in the administration of bleomycin in paediatric patients. Limit intravenous bleomycin is suitable. Bleomycin should be administered in subcutaneous or intramuscular circumstances and subcutaneous administration is adequate as part of a combination regimen the dosage is usually calculated based on the body surface (see section 4.2 Adults). Bleomycin should be given by intravenous injection, usually as part of a combination therapy. Bleomycin should be given by intravenous injection, the total dose is known as the bolus.

4.3. Contraindications

Hypersensitive to the active substance or any of the excipients listed in section 6.1

Severe idiosyncrasy

- Pulmonary infiltrate, severely impaired lung function or a history of lung damage caused by bleomycin.
- Breastfeeding (see section 4.6)

4.4. Special warnings and precautions for use

Lung toxicity is the most serious side effect associated with bleomycin, contributing to experienced oncologists.

Fatality rapidly developed pulmonary toxicity is the most serious side effect following a course of treatment. Bleomycin should only be used with caution and at a reduced dose in the event of impaired renal function. Because of the potential nonsegment pulmonary toxicity, the total dose of bleomycin should be reduced in patients with impaired renal function (see section 4.2 and section 5.2).

Pulmonary toxicity

Pulmonary toxicity is the most serious side effect associated with bleomycin, contributing to experienced oncologists.

Fatality rapidly developed pulmonary toxicity is the most serious side effect following a course of treatment. Pulmonary toxicity is a dose-related side effect. The incidence of pulmonary toxicity is increased when bleomycin is given in a total cumulative dose of 400 units. Pulmonary toxicity is also observed with lower doses and in patients who have received previous or concomitant treatment with other cytotoxic agents. The incidence of pulmonary toxicity is also increased when bleomycin is given by continuous infusion