Accord

Bleomycin 10000 IU Powder for solution for injection/infusion

Read of this leaflet carefully before you start using this medicine because it contains important information about its use.

Purpose of the leaflet

The purpose of this leaflet is to give you important information about the medicine with the following description:

1) Squamous cell carcinoma

- Live vaccines: there is a risk of serious or life-threatening infections caused by the vaccine. Vaccinations with live medicines.

2) Other medicines and Bleomycin complications.

- You have a cough and/or are short of breath, this can be a sign of the adverse effects of bleomycin on the lungs. In

Warnings and precautions

- If you have an acute lung infection or severe lung impairment;

3) Testicular tumours

- Elderly patients (from the age of 60)

4. Possible side effects

- Men who wish to father children in the future should seek advice on storing sperm before starting treatment with

5. How to take Bleomycin

- You may need to have your treatment stopped.

6. Possible side effects

- The dose might require adjustment when bleomycin is used in combination therapy.

3. How to use Bleomycin

- You may need to have your treatment stopped.

2. What you need to know before you are given Bleomycin

- The dose might require adjustment when bleomycin is used in combination therapy.

1. What Bleomycin is and what it is used for

- The medicine should be avoided during pregnancy.

Bleomycin Powder for solution for injection/infusion contains sodium.

The medicine should be avoided during pregnancy.

- If you have given more Bleomycin than you should

- If you have missed an injection, please talk with your treating doctor, to clarify if and how to make up for the missed

- If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

- If you suddenly stop taking Bleomycin without consulting a doctor, the original symptoms may recur.

- You may need to have your treatment stopped.

- If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

- Common (may affect up to 1 in 10 people)

- The use of bleomycin should be avoided during pregnancy, especially during the first 3 months.

- Animal studies have shown that this medicine can harm the embryo.

- Wessling Hungary Kft

- Middlesex HA1 4HF

- Sage House, 319, Pinner Road, Harrow

- United Kingdom

- Manufacturer

- United Kingdom

- Address of the manufacturer:

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- Address of the manufacturer:
1. What Bleomycin is and what it is used for

Bleomycin is an anti-cancer medicine. It is used:

- to treat various types of cancer such as testicular cancer, lung cancer, lymphoma, head and neck cancer, and other types of malignancy;

- to treat squamous cell carcinoma, a type of skin cancer;

- to treat non-Hodgkin lymphoma;

- to treat certain types of lung cancer;

- to treat certain types of breast cancer.

2. How to take Bleomycin

Bleomycin is usually given as an injection or as a drip. The doctor will calculate the required quantity for you, based on the dosage details specified later.

3. How much Bleomycin is in each vial

Each vial contains 15,000 International Units (I.U.) of bleomycin (as bleomycin sulphate).

4. How to prepare Bleomycin

Dissolve the contents of a vial in 1-5 mL physiological saline solution. Since repeated i.m. injections at the same site may cause local inflammation, the injection should be given into a new area. The toxic effects are the same as with intravenous injection or infusion.

5. How to store Bleomycin

Store in a refrigerator (2°C - 8°C).

6. What to do if you forget to take Bleomycin

If you take an extra dose of Bleomycin, you should:

- not take it again;
- continue taking the next dose on the schedule;
- do not take any extra doses.

7. What to do if you take too much Bleomycin

If you take too much Bleomycin, talk to the hospital pharmacist or nurse.

8. What are the possible side effects of Bleomycin

Bleomycin can cause immediate and delayed side effects. Fever on the day of injection is the earliest reaction. Loss of doxorubicin (an anti-cancer medicine) reduces the risk of skin reactions.

- nausea and vomiting;
- loss of appetite;
- hair loss;
- reduced blood counts (red blood cells, platelets, white blood cells);
- kidney damage;
- lung damage;
- liver damage;
- heart problems;
- infections;
- skin reactions;
- bleeding problems;
- other side effects not listed in this leaflet. See section 4.

9. Special precautions for storage

Store in the original container, tightly closed, in a cool and dry place.

10. Disposal of unused medicines

Ask your pharmacist how to dispose of any medicines you no longer use. These measures will help protect the environment.

11. Medicines for children

Not known.

12. Driving and using machines

If you develop any of the following side effects, tell your doctor immediately:

- reduced ability to drive;
- reduced ability to use machines that require you to be alert.

13. Pregnancy and lactation

Animal studies have shown that this medicine can harm the embryo.

14. Efﬁcacy and safety in the elderly

Elderly patients (from the age of 60)

15. Effect on ability to drive and use machines

If you develop any of the following side effects, tell your doctor immediately:

- reduced ability to drive;
- reduced ability to use machines that require you to be alert.

16. How to report side effects

If you think you have had a side effect caused by this medicine, talk to the hospital pharmacist or nurse.

17. Legal category

This medicinal product is a prescription-only medicine.

18. Marketing Authorisation Holder

Accord Healthcare Limited

19. Manufacturer

Manufactured by: Accord Healthcare Limited

20. Product licence number

United Kingdom

21. Module 2 information

This leaflet has been revised in 2018