

PACKAGE LEAFLET: INFORMATION FOR THE USER

BLEO-KYOWA® Powder for solution for injection 15,000 IU

Bleomycin sulphate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bleo-Kyowa is and what it is used for
2. What you need to know before you use Bleo-Kyowa
3. How to use Bleo-Kyowa
4. Possible side effects
5. How to store Bleo-Kyowa
6. Contents of the pack and other information

1. WHAT BLEO-KYOWA IS AND WHAT IT IS USED FOR

Bleo-Kyowa is an anti-cancer medicine (chemotherapy) used for treating certain types of cancer. Bleo-Kyowa is used to treat cancer known as squamous cell carcinoma which can affect the mouth, nose, throat, skin, cervix or external genitalia.

It is also used to treat Hodgkin's disease and other types of cancer of the blood, as well as to treat fluid producing cancers in the cavity around the lungs or in the abdomen, and to treat testicular teratoma.

Bleo-Kyowa is also of value in treating malignant melanoma (a type of skin cancer) and thyroid, lung and bladder cancer.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BLEO-KYOWA

Do not use Bleo-Kyowa:

- if you are allergic to bleomycin or to any similar anti-cancer medicine
- if you have a chest infection
- if you have scarring of the lungs
- if you have greatly reduced lung function.

If any of these apply to you, tell your doctor.

Warnings and precautions

Talk to your doctor before using Bleo-Kyowa if you have or have recently had any of the following:

- kidney problems
- lung problems or you have been receiving oxygen
- severe heart disease
- liver function that is impaired
- chicken pox
- radiation to the chest.

You must also tell your doctor if you have an operation planned, as it may be necessary to adjust your treatment with Bleo-Kyowa.

Other medicines and Bleo-Kyowa

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, as some medicines could interact with Bleo-Kyowa.

When Bleo-Kyowa is used with vinca alkaloids (another type of cancer drug) to treat cancer of the testes, Raynaud's disease (poor blood circulation which makes the toes and fingers numb and pale) has been reported.

Use of Bleo-Kyowa together with cisplatin or radiation to the chest can cause interstitial pneumonia (serious inflammation of the lungs) and pulmonary fibrosis (scarring of the lungs which leads to shortness of breath). Use of Bleo-Kyowa with clozapine should be avoided, as it may cause more severe reduction in number of white blood cells which makes infections more likely (agranulocytosis).

Use of cytotoxics (medicines that kill cancer cells) may lower the absorption of phenytoin.

Pregnancy, breast-feeding and fertility

If you are pregnant, breast-feeding, or think you may be pregnant do not take this medicine.

If you are planning to have a baby, ask your doctor for advice before using Bleo-Kyowa.

Driving and using machines

A few people have reported that they feel tired or weak after the treatment. Do not drive or use any tools or machines if you are affected.

3. HOW TO USE BLEO-KYOWA

Bleo-Kyowa powder from one or more vials will be dissolved in saline (a weak salt solution that mixes well with body fluids). The solution is usually given by injection into muscle tissue or a blood vessel or into the chest or abdominal cavity depending on the type of cancer. Occasionally, it is injected directly into a tumour.

The usual treatment is for 2 or 3 days in one week and may be repeated in subsequent weeks. Sometimes the treatment is given on consecutive days for up to 5 or 10 days.

The precise dosage, frequency of dosing and duration of treatment with Bleo-Kyowa will depend on your age, weight, medical condition and whether Bleo-Kyowa is being given in combination with other drug treatment.

If other medicines or radiotherapy are also being used in your treatment or if you have kidney disease or reduced kidney function, the amount of Bleo-Kyowa given to you may be reduced.

The total dose of the medicine given in a lifetime should not go beyond 360×10^3 IU. Your doctor will keep track of your total dose.

Use in children and adolescents

The dose is calculated in relation to child body weight and such treatment will probably take place under the supervision of a specialist treatment centre.

If during treatment you develop a dry cough, breathlessness, rapid breathing or anything else which suggests your lungs might be affected, you may require to be monitored by X-rays of your chest that could continue up to 4 weeks after the end of treatment.

If you are given more Bleo-Kyowa than you should

If you have been accidentally given a higher dose you may experience symptoms such as fever, low blood pressure and rapid pulse. Your doctor may give you supportive treatment for any symptoms that may occur.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. These might occur at the time of treatment or might occur at some later time.

If you notice any of the following reactions **tell your doctor immediately:**

- breathlessness
- inflammation of the lungs (interstitial pneumonia) – fever, chills, shortness of breath or a cough
- severe allergic reaction – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint.

These are serious side effects. You may need urgent medical attention.

If you experience any of the following **tell your doctor or nurse as soon as possible:**

Very common: (these may affect more than 1 in 10 patients)

- fever on the day of treatment
- loss of appetite and weight loss
- nausea and vomiting
- lung problems
- sore mouth and mouth ulcers
- changes in skin colour, or itchy skin
- hardening, thickening, redness, tenderness or swelling of the tips of the fingers
- hair loss
- ridging of nails, blisters on pressure points e.g. elbows
- numbness, pain or colour changes to the fingers, toes and tip of the nose, and hardening and tightening of skin

Common: (these may affect between 1 in 10 and 1 in 100 patients)

- headache
- bleeding
- skin rash, redness of the skin
- soreness at the corners of the mouth

Uncommon: (these may affect between 1 in 100 and 1 in 1,000 patients)

- dizziness
- changes in urinating or pain when urinating
- low white blood cell count
- liver problems
- blood vessel changes (narrowed or enlarged)
- diarrhoea
- pain, swelling, redness or tenderness at the site of the injection or at the site of the tumour

Other side effects which may occur are:

- overwhelming infection (sepsis)
- severe reduction in blood cells
- reduction in blood platelets
- reduction in red blood cells
- reduction in white blood cells
- chest pain
- heart attack
- reduced blood flow to the fingers, toes and tip of the nose
- blood clots
- blood clotting
- a type of stroke (cerebral infarction)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BLEO-KYOWA

Keep this medicine out of the sight and reach of children.

Bleo-Kyowa should be kept in its original packaging and stored at 2-8°C.

This medicine will normally be stored by the doctor providing your treatment or by another qualified person such as a nurse or pharmacist.

Avoid contact of Bleo-Kyowa on the skin.

Do not use this medicine after the expiry date which is stated on the label after “Exp.”. The expiry date refers to the last day of that month.

After being treated with Bleo-Kyowa, any remaining bleomycin solution or equipment used for the treatment will be safely disposed of by your nurse or doctor. Do not throw away medicines via wastewater or household waste. These measures will help protect the environment.

6. FURTHER INFORMATION

What Bleo-Kyowa contains

- The active substance is bleomycin sulphate
- There are no other ingredients

What Bleo-Kyowa looks like and contents of the pack

Bleo-Kyowa is a white to yellow-ish powder which is mixed with saline before injection. It is packaged in glass vials with a rubber stopper and aluminium seal.

Marketing Authorisation Holder

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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Bleo-Kyowa.

This leaflet was last revised in 09/2017.