

**Module 1.3.2: Approved Patient Information Leaflet**

**Information for the Patient about**

**CIPLA BLEOMYCIN**

**SCHEDULING STATUS:**

S4

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

**CIPLA BLEOMYCIN** containing **bleomycin sulphate** 7,5 mg (Powder for solution for injection).

**Read all of this leaflet carefully before you start receiving CIPLA BLEOMYCIN:**

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **CIPLA BLEOMYCIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

**WHAT CIPLA BLEOMYCIN CONTAINS:**

Each vial contains 7,5 mg bleomycin sulphate equivalent to 15 units of bleomycin. Bleomycin is a cytostatic agent, in other words a medicine for the treatment of cancer.

### **WHAT CIPLA BLEOMYCIN IS USED FOR:**

**CIPLA BLEOMYCIN** is used to treat several types of cancer, including:

- Squamous cell (a flat cell resembling a scale) skin cancers.
- Squamous cell cancers of the head and neck, including the oesophagus.
- Squamous cell cancer of the penis and uterine (womb) cervix.
- Choriocarcinoma (a cancer arising from the placenta).
- Embryonal carcinoma of the testes.
- Certain lymphomas (cancers of the lymph tissue).

### **BEFORE YOU RECEIVE CIPLA BLEOMYCIN:**

**Do NOT receive CIPLA BLEOMYCIN if you:**

- Are pregnant or breastfeeding (see "**Pregnancy and breastfeeding**").
- Are hypersensitive or allergic to bleomycin or any of the ingredients of **CIPLA BLEOMYCIN**.

### **Take special care with CIPLA BLEOMYCIN:**

The presence of other medical conditions may affect the use of **CIPLA BLEOMYCIN**.

Tell your doctor or pharmacist:

- If you suffer from impaired kidney function.
- If you suffer from impaired lung function, especially after previous therapy with **CIPLA BLEOMYCIN**, or if you smoke and are often short of breath or cough frequently.

- If you are older than 70 years of age, as you are then more likely to develop lung complications from treatment with **CIPLA BLEOMYCIN**.
- If you are scheduled for any kind of surgery, you must tell your doctor or dentist that you are receiving, or have received, **CIPLA BLEOMYCIN**, since patients receiving oxygen as part of general anaesthesia have an increased risk of lung complications from **CIPLA BLEOMYCIN** therapy.
- If you are receiving, or have received, radiation therapy for cancer, as this may increase your risk to develop complications, such as low white and red blood cell counts, mouth ulcers or lung complications. **CIPLA BLEOMYCIN** may also become less effective.

Therapy with **CIPLA BLEOMYCIN**, particularly in older patients, can lead to pneumonitis (inflammation of the lung tissue) and may cause coughing, shortness of breath and weakness (see "**POSSIBLE SIDE-EFFECTS**"). It may even result in death. The earliest symptom is shortness of breath. You or a family member should report any such abnormalities to your doctor as a matter of urgency. Your doctor will monitor your lung function very closely while you are on treatment with **CIPLA BLEOMYCIN**. You will have to go for chest X-rays every week or second week. Based on the results of special investigations, your doctor may decide to stop treatment with **CIPLA BLEOMYCIN**.

The most frequent side-effects with **CIPLA BLEOMYCIN** therapy involve skin reactions. Serious skin reactions may develop late in the course of therapy, usually in

the second or third week of treatment and appears to be related to cumulative dose. These reactions include widespread reddening of the skin, itching, painful ulceration, particularly at pressure points (such as finger tips and elbows), rash, striae, blister formation, thickening, darkening (hyperpigmentation) and tenderness of the skin. Nail changes, hair loss, and ulcers in the mouth or corners of the lips are common. Your doctor may decide to stop treatment with **CIPLA BLEOMYCIN** because of these reactions. You may also develop inflammation, pain, redness and swelling at the site of injection. The skin side-effects of **CIPLA BLEOMYCIN** are slowly reversible following completion of therapy. Some patients have develop contact dermatitis (a form of eczema that is characterised by a rash that itches) where **CIPLA BLEOMYCIN** came into direct contact with the skin.

If you have been diagnosed with HIV/AIDS and develop any skin lesion, including any of those listed above, please report to your doctor immediately.

**Pregnancy and breastfeeding:**

The use of **CIPLA BLEOMYCIN** during pregnancy and breastfeeding is contraindicated.

Women who are able to have children must use contraceptive measures during treatment with **CIPLA BLEOMYCIN**.

**If you are pregnant or breastfeeding your baby while receiving CIPLA BLEOMYCIN, please consult your doctor, pharmacist or other healthcare professional for advice.**

**Driving and using machinery:**

Do not drive or use machinery if you are affected (e.g. feel tired or weak or dizzy) after treatment with **CIPLA BLEOMYCIN**.

**Taking other medicines with CIPLA BLEOMYCIN:**

**If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of CIPLA BLEOMYCIN with these medicines may cause undesirable interactions. Please consult your doctor or pharmacist, or other healthcare professional for advice.**

In particular tell your doctor or pharmacist if you are using:

- Other medicines for the treatment of cancer, including medicines such as cisplatin and vinblastine, as you may develop complications from combination therapy, such as heart attack, stroke, small blood clots, kidney failure or inflammation of the arteries to your brain (see "**POSSIBLE SIDE-EFFECTS**").
- Any other medicines that may influence kidney function. Ask your doctor if you are unsure.
- Medicines to increase white blood cell counts, as this may increase your risk of developing lung complications from therapy with **CIPLA BLEOMYCIN**.

- Phenytoin, as the combination with **CIPLA BLEOMYCIN** should be avoided.
- Other medicines that are toxic to mucous membranes, since mouth or genital ulcers may get worse if **CIPLA BLEOMYCIN** is combined with such medicines or with radiation therapy.

### **HOW TO RECEIVE CIPLA BLEOMYCIN:**

**CIPLA BLEOMYCIN** will be administered either into your veins, muscles or under the skin in a dosage calculated by your treating doctor. You will usually receive treatment with **CIPLA BLEOMYCIN** either once a week or twice a week.

There is a possibility of having an allergic reaction to **CIPLA BLEOMYCIN**. This would usually occur after either your first or second dose. You could experience symptoms such as rash, low blood pressure, mental confusion, fever, chills or wheezing. If you suffer from lymphoma, your doctor will give you a lower dose for your first two treatments with **CIPLA BLEOMYCIN** to ensure that you are not allergic to it.

Your doctor will decide how long treatment with **CIPLA BLEOMYCIN** will last.

If you have the impression that **CIPLA BLEOMYCIN** is too strong or too weak for you, please discuss this with your doctor.

**If you received more CIPLA BLEOMYCIN than you should:**

If you received more **CIPLA BLEOMYCIN** than you should, the doctor will attend to the overdose.

**POSSIBLE SIDE-EFFECTS:**

**CIPLA BLEOMYCIN** can have side-effects.

**Not all side-effects reported for CIPLA BLEOMYCIN are included in this leaflet.**

**Should your general health worsen while receiving CIPLA BLEOMYCIN, please consult your doctor, pharmacist or other healthcare professional for advice.**

Serious side-effects that you, or a family member, should report to your doctor immediately include:

- Severe shortness of breath, which may be an indication of lung problems, which are potentially the most serious side-effect of **CIPLA BLEOMYCIN** therapy and may result in lung toxicity and death.
- Pneumonia – fever, chills, cough, shortness of breath.
- Allergic reactions, which may present with confusion, fever, chills, wheezing, shortness of breath, skin rash and swelling, difficulty in swallowing.
- Chest pain, radiating into the jaw or down the left arm, accompanied by shortness of breath, weakness and nausea, as this may indicate a heart attack.
- Weakness or paralysis affecting one side of the body, confusion or loss of consciousness, difficulty speaking, or any other symptoms related to a stroke.

- Blue discolouration of the fingers or toes, as this may indicate occlusion of blood vessels due to small blood clots.
- Severe headache.
- Increased or decreased frequency of urination, discolouration of urine, inability to pass urine, swelling and confusion, as this may indicate damage to the kidneys.

The most frequent side-effects whilst being treated with **CIPLA BLEOMYCIN** include those affecting the skin. These include widespread reddening of the skin, itching, painful ulceration, particularly at pressure points (such as finger tips and elbows), rash, striae, blister formation, thickening, darkening (hyperpigmentation) and tenderness of the skin, nail changes, hair loss, and ulcers in the mouth or corners of the lips. Please report any such side-effects to your doctor as soon as possible as these effects may become serious (see "**Take special care with CIPLA BLEOMYCIN**").

Check with your doctor or pharmacist if any of the following side-effects continue or become bothersome:

- Loss of appetite and weight loss, which may persist long after treatment with **CIPLA BLEOMYCIN** has been discontinued.
- Dizziness or fatigue due to low blood pressure.
- Raynaud's phenomenon (discolouration of fingers or toes after exposure to heat or cold or in response to emotional stress).

- Pain following injection of **CIPLA BLEOMYCIN** into the cavity surrounding the lungs.
- Nausea and vomiting.
- Fever and chills. You may develop transient fever 3 to 5 hours after injection of **CIPLA BLEOMYCIN** into your veins.
- Inflammation and pain at the site of injection.
- Sore mouth and mouth ulcers.

Other side-effects with **CIPLA BLEOMYCIN** for which you will be monitored, include:

- Liver damage.
- Kidney damage.

Please tell your doctor or pharmacist of any other undesirable effects you think may be due to receiving **CIPLA BLEOMYCIN**, especially if not mentioned in this leaflet.

**STORAGE AND DISPOSING OF CIPLA BLEOMYCIN:**

The centre where you receive treatment will store and dispose of **CIPLA BLEOMYCIN** on your behalf.

The lyophilised product should be stored between 2 and 8 °C and protected from light.

Store vials in carton until required for use.

The reconstituted product is for single use only. Discard any unused portion.

**KEEP OUT OF REACH OF CHILDREN.**

**PRESENTATION OF CIPLA BLEOMYCIN:**

5 ml, clear, colourless, single-dose injection vial with a grey stopper and 20 mm aluminium tear-off seal, with red flip-off lid, containing 15 units of bleomycin in the form of a powder or cake, supplied in an outer carton made of white back board, type IV carton.

**IDENTIFICATION OF CIPLA BLEOMYCIN:**

Lyophilised product: A sterile, white to off-white lyophilised powder or cake supplied in clear glass single-dose vial of 5 ml capacity.

Reconstituted product: Clear, colourless solution, free from visible particles.

**REGISTRATION NUMBER:**

45/26/0185

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF**

**REGISTRATION:**

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530

RSA

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