PATIENT INFORMATION LEAFLET

BLEOCIP

SCHEDULING STATUS:

S4

BLEOCIP 15 units powder for solution for injection

Bleomycin sulphate 7,5 mg

Sugar free

Read all of this leaflet carefully before you are given BLEOCIP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What BLEOCIP is and what it is used for

BLEOCIP is an antitumour antibiotic with cytotoxic activity, which means that it is a medicine that is used to treat cancer. It acts by inhibiting the growth tumours.

BLEOCIP 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).

2. What you need to know before you take BLEOCIP

BLEOCIP should not be administered to you:

- If you are hypersensitive (allergic) to bleomycin or any of the other ingredients of BLEOCIP (listed in section 6).
- If you are pregnant or breastfeeding (see pregnancy and breastfeeding).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you are receiving or have received radiation therapy for your lungs or chest area.

- If you suffer from impaired kidney function, as you may require a reduced dose.
- If you are sexually active as you will require reliable contraception during therapy and up to 6 months after therapy.
- If you suffer from impaired lung function, especially after previous therapy with BLEOCIP, or if you smoke and are often short of breath or cough frequently.
- There is a risk that you may develop diseases that cause scarring of the lungs while on treatment with BLEOCIP. Therefore, you will likely have to undergo frequent chest x-rays and measurements of lung function. These tests will continue for up to 4 weeks after completion of therapy and you will be kept under review for approximately 2 months.
- If you develop lung disease as mentioned above, your treatment with BLEOCIP will stop immediately and you will be treated with antibiotics and corticosteroids (anti-inflammatory medicines).
- If you are older than 70 years of age, as you are then more likely to develop lung complications from treatment with BLEOCIP.
- If you are scheduled for any kind of surgery, you must tell your doctor or dentist that you are receiving, or have received, BLEOCIP, since patients receiving oxygen as part of general anaesthesia have an increased risk of lung complications from BLEOCIP therapy.
- If you are experiencing shortness of breath, as treatment with BLEOCIP may cause damage to the lung walls.

- 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. BLEOCIP may also become less effective.
- If you have severe heart disease or liver disease as you may be at risk of greater toxicity while on treatment with BLEOCIP.
- If you have AIDS, as treatment with BLEOCIP may need to be stopped if you develop side effects affecting the skin.
- If you are currently undergoing treatment with cisplatin, as your dose of BLEOCIP may need to be reduced.
- Treatment with BLEOCIP may cause an allergic reaction, therefore your doctor should initially give you a test dose and only administer the full dose if there is no reaction.
- If you are currently taking other anti-cancer medicines as there is a risk of developing a heart attack.

The most frequent side effects with BLEOCIP 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 fingertips 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 BLEOCIP because of these reactions. You may also develop inflammation, pain, redness and swelling at the site of injection. The skin side-effects of BLEOCIP 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 BLEOCIP came into direct contact with the skin.

Other medicines and BLEOCIP

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines)

- 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 section 4). Other medicines include mitomycin, cyclophosphamide, methotrexate and gemcitabine.
- Any other medicines that may influence kidney function e.g., cisplatin. Ask your doctor if you are unsure.
- If you are receiving rediation therapy as this can seriously increase your risk of lung damage.
- If you are to undergo any procedures that require the administration of oxygen, as this will increase the possibility of lung damage.
- Medicines to increase white blood cell counts, as this may increase your risk of developing lung complications from therapy with BLEOCIP.

- If you are taking digoxin, as its effect may be reduced whilst on treatment with BLEOCIP.
- If are currently on treatment with phenytoin and phosphophentoin, as BLEOCIP may reduce their effect which may cause seizures.
- If you are taking clozapine, as it may decrease your white blood cell count.
- If you are taking antibiotics e.g., gentamicin, amikacin and ticarcillin and their effects may be reduced which can cause resistance.
- If you are taking cyclosporine or tacrolimus, as it may cause your immune system to become supressed.
- Other medicines that are toxic to mucous membranes, since mouth or genital ulcers may get worse if BLEOCIP is combined with such medicines or with radiation therapy.
- If you are planning to receive any live vaccines as this may lead to serious or life-threatening infections if your immune system is weakened while on treatment with BLEOCIP.

Pregnancy, breastfeeding and fertility

The use of BLEOCIP during pregnancy and breastfeeding is contraindicated.

Both male and females should take adequate contraceptive measures up to six months after treatment with BLEOCIP has been completed.

Genetic counselling and advice on sperm conservation should be sought before treatment with BLEOCIP because of the possibility of irreversible infertility due to BLEOCIP treatment.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

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

It is not always possible to predict to what extent BLEOCIP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BLEOCIP affects them.

3. How to take BLEOCIP

You will not be expected to give yourself BLEOCIP. It will be given to you by a person who is qualified to do so.

BLEOCIP 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 BLEOCIP either once a week or twice a week.

There is a possibility of having an allergic reaction to BLEOCIP. 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 BLEOCIP to ensure that you are not allergic to it.

Your doctor will decide how long treatment with BLEOCIP will last.

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

If you receive more BLEOCIP than you should

Symptoms of overdose with BLEOCIP include low blood pressure, fever, fast heartbeat and generalised shock.

Since a health care provider will administer BLEOCIP, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take BLEOCIP

Since a health care provider will administer BLEOCIP, it is unlikely that the dose will be missed.

4. Possible side effects

BLEOCIP can have side effects.

Not all side effects reported for BLEOCIP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BLEOCIP, please consult your health care provider for advice.

If any of the following happens, stop taking BLEOCIP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe shortness of breath, which may be an indication of lung problems, which are potentially the most serious side effects of BLEOCIP therapy and may result in lung toxicity and death. These may include lung failure, scarring of the lungs blood clots in the lungs etc.
- 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to BLEOCIP. You may need urgent medical attention or hospitilisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

- 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.
- Heart attack and chest pain.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Swelling.
- Rash and reddening of the skin.
- Itching.
- Painful ulceration particularly at pressure points such as fingertips and elbows.
- Blistering.
- Darkening and tenderness of skin.
- Nail changes and hair loss.
- Ulcers in the mouth and corners of the mouth

Less frequent side effects:

- Tumour pain.
- Decreased red and white blood cell count.
- Bleeding.

- Dizziness and confusion.
- Diarrhoea.
- Loss of appetite and weight loss, which may persist long after treatment with BLEOCIP 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 BLEOCIP into the cavity surrounding the lungs.
- Nausea and vomiting.
- Muscle and joint pain.
- Fever and chills. You may develop transient fever 3 to 5 hours after injection of BLEOCIP into your veins.
- Inflammation and pain at the site of injection.

Side effects with unknown frequency:

- Sepsis (the extreme reaction of the body to infection.
- Impaired or insufficient blood supply to the body tissue.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BLEOCIP.

You may also report any suspected side effects to Cipla Medpro (Pty) Ltd., by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free).

5. How to store BLEOCIP

The centre where you receive treatment will store and dispose of BLEOCIP on your behalf.

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

Store vials in carton until required for use.

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

Store all medicines out of reach of children.

6. Contents of the pack and other information

What BELOCIP contains

- The active substance is bleomycin sulphate 7,5 mg equivalent to 15 units of bleomycin.
- The other ingredient is 01N sodium hydroxide solution.

What BLEOCIP looks like and contents of the pack

Lyophilised product: White to off white cake in glass vial.

Reconstituted product: Clear, colourless solution.

BLEOCIP is packed in a 5 mL USP type I transparent flint glass vial, sealed by a 20 mm grey bromo butyl lyophilisation stopper and 20 mm aluminium flip-off, tear-off seal with a red flip-off disc, supplied in an outer cardboard carton.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Customer care: 080 222 6662

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