APPROVED PATIENT INFORMATION LEAFLET
DR. REDDY'S LABORATORIES (PTY) LTD.
SOPILCIN 20 mg/10 ml & 50 mg/25 ml
(SOLUTION FOR INFUSION)

SCHEDULING STATUS: S4

SOPILCIN 20 mg/10 ml, 20 mg/10 ml, Concentrate for infusion

SOPILCIN 50 mg/25 ml, 50 mg/25 ml, Concentrate for infusion

Doxorubicin hydrochloride

Contains sugar (sucrose) 94 mg/ml

Read all of this leaflet carefully before you are given SOPILCIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SOPILCIN 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. The injection will be given to you by your medical doctor or by a qualified healthcare professional under her/his supervision.

What is in this leaflet

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

1. What SOPILCIN is and what it is used for

SOPILCIN is a chemotherapy/ anti-cancer) medicine.

SOPILCIN is used to treat:

- Breast cancer that has spread (metastatic), in patients at an increased risk for heart problems;
- Ovarian cancer (cancer of the ovary);

- Multiple myeloma (a cancer of the blood) in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant. SOPILCIN is used in combination with another medicine called bortezomib to treat multiple myeloma;
- AIDS-related Kaposi's sarcoma (a cancer that causes patches of abnormal tissue to grow under the skin, in the lining of the mouth, nose, and throat or in other organs).

2. What you need to know before you use SOPILCIN

SOPILCIN should not be administered to you

- if you are hypersensitive (allergic) to doxorubicin hydrochloride, peanut or soya, or any of the other ingredients of SOPILCIN (listed in section 6);
- if you are pregnant or breastfeeding;
- if you have AIDS-related Kaposi's sarcoma that may be treated effectively with local therapy or systemic (route of administration where the entire body is affected) alpha-interferon;
- if you are younger than 18 years of age, because it is not known how the medicine will affect you.

Warnings and precautions

Special care should be taken with SOPILCIN:

- Tell your doctor if you have heart disease. A heart evaluation is recommended before starting treatment, and a heart function test will be done as your doctor prescribes.
- SOPILCIN can lower the number of white blood cells in your blood, increasing the chance of getting an infection. It can also lower the number of platelets, which are necessary for blood clotting. Check with your doctor immediately if you think you are getting an infection or if you notice any unusual bleeding or bruising. Periodic blood tests to monitor your blood count will be ordered by your doctor.
- There is a risk of developing a blood cancer such as leukaemia in patients who receive combined treatment with SOPILCIN. Your doctor may continue to do blood checks once treatment has been completed.
- Tell your doctor right away if you notice sores, discolouration or any discomfort in your mouth. These could be symptoms of oral cancer.
- This medicine may cause an infusion reaction, which can be life-threatening and requires immediate medical attention. Tell your doctor right away if you notice flushing, a rash, chest pain, a

fast heartbeat, itching, sweating, trouble breathing, facial swelling, a fever or chills, back pain, tightness in the chest and throat and/or lightheadedness or faintness while you are receiving SOPILCIN.

- If you develop a severe skin condition affecting the palms of your hands and the soles of your feet (redness, swelling and pain), inform your doctor as soon as possible.
- Tell your doctor if you have Kaposi's sarcoma and have had your spleen removed. You may be at risk for infections and must be monitored.
- The cases of interstitial lung diseases have been observed in patients receiving liposomal doxorubicin as contained in SOPILCIN , including fatal cases. The symptoms of Interstitial lung disease are cough and shortness of breath sometimes with fever which are not caused by physical activity. Seek immediate medical attention, if you experience symptoms that may be signs of interstitial lung disease.
- Tell your doctor if you are diabetic, because SOPILCIN contains sugar which may require an adjustment to the treatment of your diabetes.
- Tell your doctor if you are receiving any treatment for liver disease.

Children and adolescents

SOPILCIN should not be used in children and adolescents, because it is not known how SOPILCIN will affect them.

Other medicines and SOPILCIN

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Not all interactions with SOPILCIN are included in this leaflet.

Tell your doctor or pharmacist:

- If you are taking the cyclophosphamide, taxanes or 6-mercaptopurine (medicines used in the treatment of certain cancers);
- About any other cancer treatments you are on or have been taking, as particular care needs to be taken with treatments which reduce the number of white blood cells, as this may cause further reduction in the number of white blood cells.

If you are unsure about what treatments you have received or any illnesses you have had, discuss these with your doctor.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before receiving this medicine.

- Because the active ingredient, doxorubicin hydrochloride, in SOPILCIN may cause serious birth defects, SOPILCIN should not be administered during pregnancy. It is important to tell your doctor if you think you are pregnant.
- Use a highly effective method of contraception and avoid becoming pregnant while you are taking SOPILCIN and in the eight months following discontinuation of SOPILCIN treatment.
- If you are a man, you should use highly effective contraception and not father a child while receiving treatment with SOPILCIN and for six months following completion of treatment.
- Do not breastfeed during this treatment because the active ingredient doxorubicin hydrochloride may come through in the breast milk and may be harmful to nursing infants. Women must discontinue breast-feeding before starting treatment with SOPILCIN.

Driving and using machines

Do not drive or use any tools or machines if you feel dizzy or sleepy from treatment with SOPILCIN.

SOPILCIN contains soya oil

SOPILCIN contains soya oil. If you are allergic to peanut or soya, do not use this medicine.

3. How to use SOPILCIN

Usual dosages are as follows:

- If you are being treated for breast or ovarian cancer, SOPILCIN will be administered at a dose of 50 mg per square metre of your body surface area (based on your height and weight). The dose is repeated every 4 weeks for as long as the disease does not progress and you are able to tolerate this treatment.
- If you are being treated for multiple myeloma, SOPILCIN will be administered at a dose of 30 mg per square metre of your body surface area (based on your height and weight) as a 1-hour intravenous infusion immediately after bortezomib infusion on day 4 of the bortezomib 3-week regimen. The dose is repeated as long as you respond satisfactorily and tolerate treatment.
- If you are being treated for AIDS-related Kaposi's sarcoma, SOPILCIN will be administered at a

dose of 20 mg per square metre of your body surface area (based on your height and weight). The dose is repeated every 2 to 3 weeks for 2 to 3 months, then as often as necessary to maintain an improvement in your condition.

Your doctor will tell you how long your treatment with SOPILCIN will last. If you have the impression that the effect of SOPILCIN is too strong or too weak, tell your doctor or pharmacist.

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

SOPILCIN will be given to you in a drip (infusion) into a vein. Depending on the dose and indication, this may take from 30 minutes to more than one hour (i.e., 90 minutes).

If you receive more SOPILCIN than you should

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

If you miss a dose of SOPILCIN

Since a healthcare provider will administer SOPILCIN, it is unlikely that the dose will be missed. Inform your doctor if you are unable to present for treatment on your scheduled date.

4. Possible side effects

SOPILCIN can have side effects.

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

During the infusion of SOPILCIN, the following reactions may occur:

- Flushing of the face, shortness of breath, chills, tightness in the chest and/or throat, low or increase in blood pressure, rapid heartbeat, puffing of the face, fever, dizziness, chest pain, back pain, itching, rash, sweating and fainting.
- In very rare cases, seizures (convulsions) have occurred.
- Stinging or swelling of the skin at the site of injection may also occur. If the drip stings or hurts while you are receiving a dose of SOPILCIN, tell your doctor immediately.

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

Side effects that occur frequently:

- you develop fever, feel tired, or if you have signs of bruising or bleeding;
- redness, swelling, peeling or tenderness, mainly on the hands or feet ('hand foot' syndrome). These effects have been seen very commonly and are sometimes severe. In severe cases, these effects may interfere with certain daily activities, and may last for 4 weeks or longer before resolving completely.

  The doctor may wish to delay the start and/or reduce the dose of the next treatment (see Strategies to prevent and treat hand-foot syndrome);
- sores in mouth, severe diarrhoea or vomiting or nausea;
- infections, including lung infections (pneumonia) or infections that may affect your vision;
- being short of breath;
- severe stomach pain;
- severe weakness/ fainting.

Side effects that occur less frequently:

- cardiac arrest (heart stops beating); heart failure, in which the heart does not pump enough blood to the rest of the body, which makes you short of breath and may lead to swollen legs;
- blood clot that moves to the lungs, causes chest pain and makes you short of breath;
- swelling, warmth, or tenderness in the soft tissues of your leg, sometimes with pain which gets worse when you stand or walk;
- yellowing of your skin and eyes, also called jaundice;
- serious skin reactions such as widespread peeling skin, blisters as well as mucous membrane erosion (Stevens-Johnson syndrome/toxic epidermal necrolysis).

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

Tell your doctor if you notice any of the following:

Side effects that occur frequently:

- infections, including severe infection throughout the body (sepsis), lung infections, fungal infections (including thrush and oral thrush in the mouth), herpes zoster virus infections (shingles), a type of bacterial infection (mycobacterium avium complex infection), urinary tract infection, infection of the

hair roots, infected or irritated throat, infected nose, sinuses or throat (cold), infection of the vagina;

- decrease in the number of white blood cells, which can increase the chances of infections. Anaemia (reduction in red blood cells) may cause tiredness, and decreased platelets in the blood may increase the risk of bleeding. In rare cases, having low white blood cells may lead to severe infection. It is because of some of the potential changes in your blood cells that you will have regular blood tests. Some of these effects may be related to your disease and not to SOPILCIN;
- loss of appetite, muscle wasting i.e., muscle mass loss with or without fat mass loss, not enough water in the body (dehydration), low levels of calcium, potassium or sodium in the blood;
- confusion, feeling anxious, feeling sad, problems sleeping;
- general feeling of tiredness, weakness, numbness, loss of sensation, feeling of pins and needles or pain in hands and feet; altered sense of taste-that all foods taste metallic, sweet, sour or bitter, headaches, dizziness
- inflammation in the eye;
- increase in heart rate;
- high or low blood pressure, flushing, fainting;
- shortness of breath, nose bleeds, cough;
- inflammation of the mouth and lips, sores in the mouth, nausea (feeling sick), vomiting (throwing up), diarrhoea (loose stools), constipation (hard stools), indigestion, pain on swallowing, stomach pain, dry mouth;
- hair loss, peeling of the skin, blisters, dry and scaly skin, increased sweating, darkened patches or spots on the skin;
- chest and back pain, pain in hand, legs, fingers and toes, muscle spasms, muscle, joint and bone pain;
- breast pain;
- the sensation of pain and/or burning, stinging, or itching when urination;
- fever, flu-like sickness, chills, general weakness, swelling including in the leg;
- decrease in weight.

Side effects that occur less frequently:

- herpes simplex virus infections (cold sores or genital herpes), fungal infections;
- low number of all types of blood cells, increased number of 'platelets' (cells that help blood to clot);
- high levels of potassium and uric acid, low levs of magnesium;
- fits, abnormal sense of touch, sleepiness;
- blurred vision or changes to vision, watery eyes;
- inflammation of the veins and formation of blood clots in the veins which could lead to blockage of blood flow to your lungs causing difficulty breathing, chest pain and palpitations.
- difficulty breathing, tightness in the throat;
- passing gas, inflammation of the gums, swelling of the tongue;
- skin problems or rashes, including flaky or peeling skin, allergic skin rash, ulcer (sore) or hives on the skin, discoloured skin, change in the natural colour (pigment) of the skin, small red or purple spots caused by bleeding under the
  skin, nail problems, acne, the painless separation of the nail from the nail bed, increased pigmentation of the skin or mucosa;
- mucscle weakness;
- breast pain, vaginal infection, redness of the scrotum;
- kidney problems;
- the leakage of blood, lymph, or other fluid, such as an anticancer drug, from a blood vessel or tube into the tissue around it, irritation or pain where the injection is given, swelling of the face, increase in body temperature,;
- abnormal liver blood test results, increased level of 'creatinine' in the blood;
- symptoms (such as inflammation, redness or pain) come back at a part of the body that previously received radiation therapy or was previously damaged by a chemotherapy injection into a vein.

Side effects with frequency unknown:

- cancer of the blood that develops quickly and affects the blood cells (acute myeloid leukaemia), bone marrow disease that affects the blood cells (myelodysplastic syndrome), cancer of the mouth or lip;
- serious side effects on your blood;
- coughing and shortness of breath, possibly accompanied by fever, that is not brought on by

physical activity (interstitial lung disease).

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of SOPILCIN.

Strategies to prevent and treat hand-foot syndrome:

- soak hands and/or feet in basins of cool water when possible;
- keep hands and feet uncovered (no socks, gloves or shoes that are tight-fitting);
- stay in cool places;
- take cool baths during hot weather;
- avoid vigorous exercise that might cause trauma to the feet (e.g., jogging);
- avoid exposure of skin to very hot water;

Pyridoxine (vitamin B6):

- take pyridoxine (vitamin B6) at a dose of 50 to 150 mg daily beginning at the first signs of redness or tingling.

5. How to store SOPILCIN

Store all medicines out of reach of children.

Stored in a refrigerator (2 °C to 8 °C). Do not freeze.

Retain vial in carton until time of use in order to protect from light.

After dilution:

Chemical and physical in-use stability has been demonstrated for 24 hours at 2 °C to 8 °C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2 °C to 8 °C.

Partially used vials must be discarded.

Do not use SOPILCIN after the expiry date which is stated on the label and carton.

Do not use SOPILCIN if you notice that it shows evidence of precipitation or any other particulate matter.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What SOPILCIN contains

- The active substance is doxorubicin hydrochloride. Each SOPILCIN vial contains 2 mg/ml doxorubicin hydrochloride.
- SOPILCIN 20 mg/10 ml: vial contains 20 mg doxorubicin
- SOPILCIN 50 mg/25 ml: vial contains 50 mg doxorubicin
- The other ingredients are N-(carbamoyl-methoxypolyethylene glycol 2000)- 1,2-distearoyl-*sn*-glycero-3-phosphoethanolamine sodium salt (MPEG-DSPE), fully hydrogenated soy phosphatidylcholine (HSPC), cholesterol, ammonium sulfate, histidine, sucrose, water for injection, hydrochloric acid (for pH-adjustment) and sodium hydroxide (for pH-adjustment).

What SOPILCIN looks like and contents of the pack

The concentrate for infusion is translucent and red.

SOPILCIN 20 mg/10 ml: Carton containing a single use, clear glass vial closed with a rubber stopper and sealed with an aluminium seal / dark blue plastic flip-off cap.

SOPILCIN 50 mg/25 ml: Carton containing a single use, clear glass vial closed with a rubber stopper and sealed with an aluminium seal / red plastic flip-off cap.

SOPILCIN is supplied as a single vial in a pack or 10 vials in a pack.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

APPROVED PATIENT INFORMATION LEAFLET
DR. REDDY'S LABORATORIES (PTY) LTD.
SOPILCIN 20 mg/10 ml & 50 mg/25 ml
(SOLUTION FOR INFUSION)

Morningside

Sandton

2057

This leaflet was last revised in

20 May 2026

Registration numbers

SOPILCIN 20 mg/10 ml: 51/26/0265

SOPILCIN 50 mg/25 ml: 51/26/0266

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100