# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:**

S4

**PHENASEN® 10 mg/10 ml** (concentrated solution for infusion)

Arsenic trioxide, 10 mg/10 ml

Sugar free

**Read all of this leaflet carefully before you start using PHENASEN**

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

**What is in this leaflet**

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

## 1. What PHENASEN is and what it is used for

PHENASEN is used to treat acute promyelocytic leukemia or 'APL'. This is a type of myeloid leukaemia – a disease with abnormal white blood cells and abnormal bleeding and bruising.

PHENASEN is used in adult patients with:

- newly diagnosed low-to-intermediate risk APL
- those whose leukaemia has not responded to other therapies.

## 2. What you need to know before you receive PHENASEN

**Do not receive PHENASEN:**

- If you have an allergy or are hypersensitive to any medicine containing arsenic or arsenic trioxide or to any of the ingredients of PHENASEN.
- If you have heart conditions, such as heart block, congestive heart failure (a chronic progressive condition that affects the pumping power of your heart muscles) or prolonged QT intervals (the heart muscle takes longer than normal to recharge between beats).
- If you take medicines that may affect your heart.
- Impaired kidney function
- Life-threatening liver problems
- If you are pregnant or breastfeeding.

**Warnings and precautions**

**Tell your doctor or healthcare provider before being given the injection if:**

- you have allergies to any other medicines, foods, preservatives or dyes.
- If you are pregnant. It may affect your developing baby if you are given it during pregnancy.
- If you are breastfeeding as the active ingredient in PHENASEN passes into breast milk and there is a possibility that your baby may be affected.
- you have or have had any of the following medical conditions:
    - low levels of potassium, magnesium, calcium and creatinine in the body (electrolyte imbalance);

- congestive heart failure;
- rapid or irregular heart beat;
- liver problems;
- a history of kidney problems.

If any of the above apply to you, or you are not sure, talk to your doctor, pharmacist or nurse before using PHENASEN.

**Tests and checks**

Your doctor will do the following tests and checks:

- Blood tests to check the amount of potassium, magnesium, calcium and creatinine in your blood before your first dose of PHENASEN.
- Blood tests on your potassium, calcium and liver function should be repeated during your treatment with this medicine.
- An ECG (an electrical recording of the heart) before your first dose – and then twice a week when you are using the medicine.
- If you are at risk for a certain type of abnormal heartbeat (such as 'torsade de pointes' or 'QTc prolongation'), your heart will be monitored throughout your treatment.
- Your doctor may monitor your health during and after treatment since arsenic trioxide, the active substance in this medicine, may cause other cancers. Report any new and unusual side effects whenever you see your doctor.
- Follow-up of your cognitive and mobility functions if you are at risk for vitamin B1 deficiency.

**Children/ and adolescents**

Do not give PHENASEN to children under 18 years of age as it is unlikely to be safe.

**Other medicines and PHENASEN:**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Please consult your doctor, pharmacist or other healthcare professional, for advice.

Tell your doctor if you are taking any of the following medicines:

- fluid or water tablets (diuretics);
- some medicines used to treat fungal infections such as amphotericin B;
- medicines which affect heart rhythm (prolong the Q-T interval) for example:
    - some antibiotics e.g. erythromycin
    - antipsychotics e.g. thioridazine
    - some types of anti-dysrhythmic medicines e.g.quinidine;
    - antidepressants e.g.amitriptyline;
    - some antihistamines e.g. terfenadine.

**Pregnancy and breastfeeding and fertility:**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving PHENASEN.

**Pregnancy:**

PHENASEN may cause harm to the unborn baby when used by pregnant women. If you are pregnant, or you become pregnant during treatment with this medicine, you must ask your doctor for advice.

If you are able to become pregnant, you must use effective contraceptive measures during treatment with PHENASEN and for 6 months following completion of treatment.

Men must use effective contraception and not father a child while receiving PHENASEN and for 3 months following completion of treatment.

**Breastfeeding:**

Do not breastfeed during treatment with this medicine and for two weeks after the last dose. You can consider alternative option to breast milk if available. This is because the arsenic in PHENASEN passes into breast milk and can harm your baby.

**Driving and using machinery:**

PHENASEN may cause dizziness, tiredness or light-headedness and affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment (see 'Undesirable effects').

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PHENASEN affects them.

**PHENASEN is sugar free.**

**PHENASEN contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per 10mL, that is to say essentially 'sodium-free'.

## 3. How to receive PHENASEN:

Do not share medicines prescribed for you with any other person.

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

PHENASEN must only be given by a doctor or nurse under the supervision of a medical practitioner experienced in cancer treatment.

PHENASEN is given as a drip (infusion) into a vein over 1-2 hours. The infusion may last longer if you get side effects such as flushing and feeling dizzy.

Your doctor will decide what dose of PHENASEN you will receive and how long you will receive it. This depends on your medical condition and other factors, such as your weight.
Your doctor will decide exactly how long you must continue using PHENASEN.

**If you receive more PHENASEN than you should:**

Since a healthcare professional will administer PHENASEN, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage. You may have fits, muscle weakness and confusion. If you notice these signs, tell your doctor straight away who will stop treatment with PHENASEN.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**If you missed a dose of PHENASEN:**

Since a healthcare professional will administer PHENASEN, it is unlikely that the dose will be missed.

## 4. Possible side effects

PHENASEN can cause side effects.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while receiving this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- hives;

- fainting.

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

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

- chest pain;
- irregular heart beat;
- difficulty or pain when breathing;
- stroke;
- passing little or no urine;
- signs of APL differentiation syndrome as listed below:
    - unexplained fever;
    - shortness of breath, difficulty breathing;
    - and/or weight gain.

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

**Tell your doctor if you notice any of the following:**

The following side effects have been reported frequently:

- Tiredness;
- Fever;
- Nausea, vomiting, diarrhoea, stomach pain, sore mouth;
- Bleeding or bruising more easily than usual;
- Sore throat,cough, difficulty breathing, chest pain;
- Headache,difficulty sleeping;

- Fast and abormal heart beat;
- Skin rash, itching;
- Bone or joint pain;
- Numbness, aching or weakness of the arms and legs or other muscles;
- Altered moods;
- Infections;
- Tingling in the hands and feet;
- Fits or convulsions;
- Abnormal blood results – shown in tests: reduced potassium or magnesium, abnormal liver function tests including excess bilirubin or 'gamma-glutamyltransferase'
- Signs of hyperglycaemia (high blood sugar):
    - large amounts of urine;
    - excessive thirst;
    - dry mouth and skin.

The above list includes serious side effects, if you have them, you may have had a serious allergic reaction to PHENASEN. You may need urgent medical attention or hospitalisation.

The following side effects have been reported less frequently:

- Disturbances in the electrolytes in the body, e.g. low or high levels of magnesium, high levels of sodium and high levels of potassium;
- Disturbances in the metabolic systems in the body, e.g. high concentrations of ketone bodies, formed by the breakdown of fatty acids (ketoacidosis) and too much bilirubin in the blood (when red blood cells break down, a substance called bilirubin is formed) (hyperbilirubinaemia) and abnormal liver function;
- Pain;

- Bleeding in the lungs, excess fluid builds around the lung (pleural effusion), a deficiency in the amount of oxygen reaching the tissues (hypoxia);
- Fluid around the heart;
- A reduction of the number of white cells in the blood (leucopenia) and inflammation of a blood vessel or blood vessels (vasculitis);
- General inflammation of the skin (dermatitis) and redness of the skin (erythema);
- Bleeding;
- Blood clots;
- Suppression of the immune system, which may lead to shingles (herpes zoster).

Contact your doctor, pharmacist or other health care professional for advice as soon as possible if you suffer from any of the above side effects.

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 PHENASEN.

## 5. How to store PHENASEN

- Store at or below 30 ºC.
- Store all medicines out of reach of children.
- Store in the original package / container.
- Do not store in a bathroom.

- Do not use after the expiry date stated on the label / carton / vial.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not use PHENASEN if you notice if the solution is cloudy, discoloured, turbid, or a precipitate or particles are present. The solution is normally clear and colourless.

## 6. Contents of the pack and other information

**What PHENASEN contains:**

The active substance is arsenic trioxide.

Each 10 mL contains 10 mg arsenic trioxide.

The other inactives are:

- Hydrochloric acid (for pH adjustment), sodium hydroxide and water for injection.

**What PHENASEN looks like and contents of the pack**

The product is packed in a 10 mL clear, colourless Type I glass vial, with a grey chlorobutyl rubber stopper that is moulded with a Flurotec film and then coated in silicon oil and sealed with and aluminium seal with a red flip-off button. 10 vials are packed in a cardboard carton.

PHENASEN is a clear, particle-free, colourless concentrated solution for infusion. It is a sterile solution for single use. PHENASEN must be diluted before use.

**Holder of Certificate of Registration**

Key Oncologics (Pty) Ltd

39 Eleventh Avenue

Houghton Estate, 2198

Johannesburg

RSA

**This leaflet was last revised in**

6 February 2023

**Registration number**

52/26/0019

**Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website

<Item code to be allocated>