Applicant : Eurolab (Pty) Ltd
Proprietary name : Azacitidine Eurolab
Dosage form and strength : Lyophilised powder for suspension for injection
Date of submission : 30 April 2026
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APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

AZACITIDINE EUROLAB (Lyophilised powder for suspension for injection)

Azacitidine

Contains sugar: Each vial contains 100 mg mannitol

Read all of this leaflet carefully before you are given AZACITIDINE EUROLAB

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

What is in this leaflet

1. What AZACITIDINE EUROLAB is and what it is used for

2. What you need to know before you are given AZACITIDINE EUROLAB

3. How AZACITIDINE EUROLAB will be given to you

4. Possible side effects

5. How to store AZACITIDINE EUROLAB

6. Contents of the pack and other information

1. WHAT AZACITIDINE EUROLAB IS AND WHAT IT IS USED FOR

AZACITIDINE EUROLAB contains a medicine called azacitidine.

AZACITIDINE EUROLAB is an anti-cancer medicine which belongs to a group of medicines called ‘anti-metabolites’. AZACITIDINE EUROLAB prevents cancer cells from growing.

AZACITIDINE EUROLAB is used in adults who are not able to have a stem cell transplantation to treat:

- higher-risk myelodysplastic syndromes (MDS), a group of bone marrow disorders in which the bone marrow does not produce enough healthy blood cells;
- chronic myelomonocytic leukaemia (CMML) a type of cancer of the blood-forming cells of the bone marrow;
- acute myeloid leukaemia (AML), a cancer of the blood cells, characterised by the rapid growth of abnormal white blood cells that accumulate in the bone marrow and interfere with the production of normal blood cells.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN AZACITIDINE EUROLAB

You should not receive AZACITIDINE EUROLAB

- if you are hypersensitive (allergic) to azacitidine or any of the other ingredients of AZACITIDINE EUROLAB (see section 6),
- if you have advanced liver cancer,
- do not receive live vaccines while being treated with AZACITIDINE EUROLAB.
- if you are pregnant or breastfeeding your baby,
- if you are younger than 18 years old.

Warnings and precautions

Special care should be taken with AZACITIDINE EUROLAB

- if you have decreased counts of platelets, red or white blood cells,
- if you have kidney disease,
- if you have liver disease,
- if you have ever had a heart condition or heart attack or any history of lung disease,
- AZACITIDINE EUROLAB may cause a rare infection of the deeper layers of skin and subcutaneous tissues. Tell your doctor if you notice any changes to your skin or if you develop a fever,
- AZACITIDINE EUROLAB may cause a condition that happens when cancer cells die quickly. Dying cells release large amounts of potassium, phosphate, and uric acid into the blood. This can cause heart or kidney problems and lead to kidney failure (tumour lysis syndrome),
- Some of the symptoms are nausea, vomiting, diarrhoea, muscle cramps, numbness, seizures, confusion and weakness. This condition may be life-threatening if it is not managed or treated,
- AZACITIDINE EUROLAB can cause a serious immune reaction called ‘differentiation syndrome’.

Blood monitoring

You will have blood tests before you begin treatment with AZACITIDINE EUROLAB and at the start of each period of treatment (called a ‘cycle’). This is to check that you have enough blood cells and that your liver and kidneys are working properly.

Use in children and adolescents

AZACITIDINE EUROLAB is not to be used to treat children and adolescents below the age of 18.

Use in elderly

Use AZACITIDINE EUROLAB with caution in the elderly, they may be more sensitive to its effects.

Other medicines and AZACITIDINE EUROLAB

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

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

This is because AZACITIDINE EUROLAB may affect the way some other medicines work. Also, some other medicines may affect the way AZACITIDINE EUROLAB works.

Pregnancy, breastfeeding and fertility

AZACITIDINE EUROLAB may be harmful to the baby, therefore it should not be used if you are pregnant.

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 professional for advice before you receive AZACITIDINE EUROLAB.

Tell your doctor straight away if you become pregnant during treatment.

If you are a woman who can become pregnant you should use a highly effective method of contraception while using AZACITIDINE EUROLAB and for 6 months after stopping treatment with AZACITIDINE EUROLAB.

You should not breastfeed when taking AZACITIDINE EUROLAB, as it is not known if AZACITIDINE EUROLAB passes into breast milk.

If you are a man, you should not father a child while receiving AZACITIDINE EUROLAB. You should use an effective method of contraception while receiving AZACITIDINE EUROLAB and for 3 months after stopping treatment with AZACITIDINE EUROLAB. You should seek counselling on sperm storage.

Female partners of male patients receiving AZACITIDINE EUROLAB should not become pregnant.

AZACITIDINE EUROLAB contains mannitol

AZACITIDINE EUROLAB contains mannitol:

- which is a type of sugar and may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using AZACITIDINE EUROLAB.
- which, on rare occasions, may cause hypersensitivity reactions and may have a laxative effect.

Driving and using machines:

AZACITIDINE EUROLAB may cause blurred vision, sleepiness or tiredness. If you experience any of these side effects, do not drive or operate machinery.

3. HOW TO RECEIVE AZACITIDINE EUROLAB

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

Your doctor will decide on the most suitable treatment for you including:

- the correct dose
- how often and for how long you should be treated and
- whether you should also receive other medicines with AZACITIDINE EUROLAB or not.

Your doctor will give you all the necessary information on your treatment plan.

Before giving you AZACITIDINE EUROLAB, your doctor will give you another medicine to prevent nausea and vomiting at the start of each treatment cycle.

The recommended dose is 75 mg per m^2 body surface area. Your doctor will decide your dose of AZACITIDINE EUROLAB, depending on your general condition, height and weight. Your doctor will check your progress and may change your dose if necessary.

AZACITIDINE EUROLAB is given every day for one week, followed by a rest period of 3 weeks. This “treatment cycle” will be repeated every 4 weeks. You will usually receive at least 4 treatment cycles.

AZACITIDINE EUROLAB will be given to you as a subcutaneous injection (injection into your thigh, abdomen or upper arm a muscle under your skin) or intravenous infusion by a doctor or nurse.

The intravenous infusion will be given over a period of 10 to 40 minutes.

Do not stop treatment early because it may affect the working of AZACITIDINE EUROLAB in treating your cancer.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you have the impression that the effect of AZACITIDINE EUROLAB is too strong or too weak, tell your doctor or pharmacist.

If you receive more AZACITIDINE EUROLAB than you should

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

If you forget to use AZACITIDINE EUROLAB

Since a healthcare will administer AZACITIDINE EUROLAB, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS

AZACITIDINE EUROLAB can have side effects.

Not all side effects for AZACITIDINE EUROLAB are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AZACITIDINE EUROLAB, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth, tongue, neck or throat, which may cause difficulty in swallowing or breathing,
- throat tightness,
- shortness of breath and wheezing,
- rash, 'hives' (raised bumps), blisters or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AZACITIDINE EUROLAB. 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:

- Drowsiness, shaking, jaundice (yellow of skin and white of eyes), abdominal bloating and easy bruising.

  These may be symptoms of liver failure and can be life-threatening.
- Swelling of the legs and feet, back pain, reduced passing of water, increased thirst, rapid, pulse, dizziness and nausea, vomiting or reduced appetite and feelings of confusion, restlessness or fatigue.

  These may be symptoms of kidney failure and can be life-threatening.
- A fever.

  This could be due to an infection as a result of having low levels of white blood cells, which can be life-threatening.
- Chest pain or shortness of breath which may be accompanied with a fever.

  This may be due to an infection of the lung called "pneumonia", and can be life-threatening.

- Bleeding.

  Such as blood in the stools due to bleeding in the stomach or gut.

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- An infection of the nose and throat or the common cold (nasopharyngitis).
- An infection of the blood caused by bacteria (sepsis). This may be due to low levels of white cells in your blood (neutropenic sepsis).
- Infection of the sinuses, lung or throat (respiratory tract).
- An infection in your urine (urinary tract infection).
- Skin infection (cellulitis).
- Pain in the gut which can result in fever and vomiting due to inflammation of the colon (diverticulitis).
- White coating covering tongue, inner cheeks, and sometimes on the roof of your mouth, gums and tonsils (oral fungal infection).
- Inflammation of the sinuses (sinusitis).
- Sore throat (pharyngitis).
- Runny nose (rhinitis).
- A viral infection causing cold sores (herpes simplex).
- Reduced red blood count (anaemia). You may feel tired and pale.
- Reduced neutrophils (type of white blood cell count (neutropenia)). This may be accompanied by a fever (febrile neutropenia). You are also more likely to get infections.

- A reduced white blood cell count (leukopenia).
- A reduced blood platelet count (thrombocytopenia). You are more prone to bleeding and bruising.
- A reduced red cell, white cell, and platelet count (pancytopenia).
- Bone marrow failure due to the low red and white blood cell and platelet counts.
- Eating disorder (anorexia), loss of appetite, low levels of potassium in the blood (hypokalaemia), increased thirst (dehydration).
- Extreme loss of weight,
- Feeling anxious (anxiety), difficulty sleeping, confusion.
- Dizziness, headache, bleeding inside your head (intracranial haemorrhage), fainting (syncope), burning sensation, numbness (hypoesthesia).
- Bleeding in the eye (eye haemorrhage), bleeding of conjunctiva (conjunctival haemorrhage).
- High or low blood pressure (hypertension or hypotension), low blood pressure that happens when you stand up from sitting or lying down making you feel faint or dizzy (orthostatic hypotension), a solid swelling of clotted blood within the tissues (haematoma).
- Small red or purple spots caused by bleeding into the skin (petechiae), itching (pruritus), rash, a discoloration of the skin resulting from bleeding underneath, typically caused by bruising (ecchymosis), a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura), hair loss (alopecia), “hives”/ itchy rash (urticaria), reddening of the skin(erythema), type of rash (rash macular).
- Being short of breath (dyspnoea), nose bleeds (epistaxis), water/fluid in the lungs (pleural effusion), being short of breath when you move (dyspnoea exertional), pain in your throat and voice box (pharyngolaryngeal pain) coughing up blood, blocked nose.
- Constipation, loose stomach, feeling sick (nausea), being sick (vomiting), bleeding gums, blood in your stools, blood spots inside your mouth, reddening and swelling on the inside of your mouth, sores on your tongue.

- Pain (includes back, bone and pain in extremity), muscle weakness, muscle spasms, joint pain (arthralgia), muscle pain (myalgia).
- Kidney failure (renal failure), blood in the urine (haematuria), painful urinating, increased levels of creatinine (picked up in blood tests).
- Fever (pyrexia), feeling tired (fatigue), physical weakness or lack of energy (asthenia), chest pain, bruising, pain, redness and swelling of at the site of injection (injection site erythema), hardened mass associated with inflammation (induration), rash, itching (pruritus), swelling (inflammation), discoloration, bleeding at injection site, general feeling of being unwell (malaise), chills, bleeding at the catheter site.

Less frequent side effects:

- Collection of pus under the skin around the anus.
- Allergic (hypersensitivity) reactions.
- A group of abnormalities that can occur as a complication during the treatment of cancer e.g., high levels of potassium, phosphorus, calcium, uric acid, blood urea nitrogen (BUN) and other nitrogen containing compounds (tumour lysis syndrome).
- Group of diseases affecting different parts of the lung (interstitial lung disease).
- Liver failure (hepatic failure), coma caused due to liver failure (progressive hepatic failure).
- A skin disease characterised by the sudden onset of fever, an elevated white blood cell count, and tender, red swellings on the skin (acute febrile neutrophilic dermatosis).
- An accumulation of acid in the body due to a failure of the kidneys to (renal tubular acidosis), “death” of the skin at the injection site (injection site necrosis).

Side effects with and unknown frequency:

- Infection of the deeper layers of skin, which spreads quickly, damaging the skin and tissue, which can be life-threatening (necrotising fasciitis).
- Serious immune reaction (differentiation syndrome) that may cause fever, cough, difficulty breathing, rash, decreased urine, low blood pressure (hypotension), swelling of the arms or legs and rapid weight gain.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Eurolab (Pty) Ltd. by email: drug-safety@eurolab.co.za.

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

5. HOW TO STORE AZACITIDINE EUROLAB

Store at or below 25 °C.

After reconstitution:

From a microbiological point of view, the medicine should be used immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 8 hours when stored between 2 and 8 °C.

If administration is to be delayed, the reconstituted product may be kept in the vial or drawn into a syringe. The product must be refrigerated (2 °C - 8 °C) immediately. After removal from refrigerated conditions, the suspension may be allowed to equilibrate to room temperature (25 °C) for up to 30 minutes prior to administration.

When stored at 25 °C, the reconstituted product should be administered within 1 hour.

Store all medicines out of reach of children.

Store in original package until use.

Do not use after the expiry date stated on the label.

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 AZACITIDINE EUROLAB contains

- The active substance is azacitidine.
- Each vial contains 100 mg azacitidine.
- The other ingredients are mannitol and water for injection.

What AZACITIDINE EUROLAB looks like and contents of the pack

- AZACITIDINE EUROLAB is a white lyophilized powder or cake
- It is presented in a 30 mL, clear, type 1 glass vial, sealed with a grey bromo-butyl, siliconised rubber stopper and white aluminium flip-off seal.

HOLDER OF CERTIFICATE OF REGISTRATION

Eurolab (Pty) Ltd.

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