Applicant : Eurolab (Pty) Ltd
Proprietary name : Azacitidine Eurolab
Dosage form and strength : Lyophilised powder for suspension for injection
Date of submission : 30 April 2026
Approval date : 28 July 2026

APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

AZACITIDINE EUROLAB (lyophilised powder for suspension for injection)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 100 mg azacitidine.

The reconstituted suspension contains 25 mg/mL azacitidine.

Contains sugar: Each vial contains 100 mg mannitol

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilised powder for suspension for injection.

A white lyophilized powder or cake.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AZACITIDINE EUROLAB is indicated for treatment of patients with myelodysplastic syndromes including the following subtypes of the French-American-British classification:

- Refractory anaemia (RA) according to the French-American-British classification (FAB) system, plus neutropenia or thrombocytopenia or requiring transfusions;
- Refractory anaemia with ringed sideroblasts (RARS) according to the FAB system, plus neutropenia or thrombocytopenia or requiring transfusions;
- Refractory anaemia with excess blasts (RAEB) according to the FAB system;
- Refractory anaemia with excess blasts in transformation (RAEB-T) according to the FAB system (or acute myeloid leukaemia with 20 to 30 % bone marrow blasts and multilineage dysplasia according to World Health Organisation (WHO) classification).
- AZACITIDINE EUROLAB is also indicated for treating adult patients with chronic myelomonocytic leukaemia (CMML) according to the FAB system.
- Acute myeloid leukaemia (AML) with > 30 % bone marrow blasts according to the WHO classification, in patients who are not eligible for hematopoietic stem cell transplantation (HSCT).

4.2 Posology and method of administration

AZACITIDINE EUROLAB should be administered under the supervision of a doctor qualified in the use of cytotoxic medicines.

Posology

The recommended starting dose for the first treatment cycle, for all patients regardless of baseline haematology laboratory values, is 75 mg/m^2 subcutaneously or intravenously, daily for seven (7) days, followed by a rest period of 21 days (28-day treatment cycle). It is recommended that patients be treated for a minimum of 6 cycles. Treatment should be continued as long as the patient continues to benefit or until disease progression.

Patients should be monitored for haematologic response/toxicity and renal toxicities (see section 4.8), a delay in starting the next cycle or a dose reduction as described below may be necessary.

Dosage Adjustment due to haematological toxicity:

Patients with baseline blood counts (i.e., White Blood Cells (WBC) > 3,0 x 10^9/L and absolute neutrophil count (ANC) > 1,5 x10^9/L, and platelets > 75,0 x 10^9/L).

If haematological toxicity is observed following AZACITIDINE EUROLAB treatment, the next cycle of AZACITIDINE EUROLAB therapy should be delayed until the platelet count and the ANC have recovered.

If recovery is achieved within 14 days, no dose adjustment is necessary. However, if recovery has not been achieved within 14 days, the dose should be reduced according to the following table.

Following dose modifications, the cycle duration should return to 28 days.

Nadir Counts		**% Dose in the next cycle, if recovery* is not achieved within 14 days**
ANC (10^9/L)	Platelets (10^9/L)	
< 1,0	< 50,0	50 %
> 1,0	> 50,0	100 %

*Recovery= counts≥ Nadir count + (0,5 x [baseline count- Nadir count])

Patients baseline blood counts (i.e., WBC < 3,0 x 10^9/L or ANC < 1,5 x 10^9/L or platelets < 75,0 x 10^9/L):

Following AZACITIDINE EUROLAB treatment, if the decrease in WBC or ANC or platelets from baseline is less than 50 %, or greater than 50 % but with an improvement in any cell line differentiation, the next cycle should not be delayed and no dose adjustment be made.

If the decrease in WBC or ANC or platelets is greater than 50 % from that prior to treatment, with no improvement in cell line differentiation, the next cycle of AZACITIDINE EUROLAB therapy should be delayed until the platelet count and the ANC have recovered.

If recovery is achieved within 14 days, no dose adjustment is necessary. However, if recovery has not been achieved within 14 days, bone marrow cellularity should be determined. If the bone marrow cellularity is > 50 %, no dose adjustments should be made.

If bone marrow cellularity is ≤ 50 %, treatment should be delayed, and the dose reduced according to the following table:

Bone Marrow Biopsy Cellularity	**% Dose in the next cycle, if recovery is not achieved within 14 days**	
	Recovery * ≤ 21 days	**Recovery * > 21 days**
15 to 50 %	100 %	50 %
< 15 %	100 %	33 %

Special populations

Patients with renal impairment

AZACITIDINE EUROLAB can be administered to patients with renal impairment without initial dose adjustment. If unexplained reductions in serum bicarbonate levels to less than 20 mEq/L occur, the dose should be reduced by 50 % on the next cycle. If unexplained elevations in serum creatinine or blood urea occur, the next cycle should be delayed until values return to normal or baseline and the dose should be reduced by 50 % on the next treatment cycle (see section 4.4).

Patients with hepatic impairment

No studies have been conducted in MDS patients with hepatic impairment. AZACITIDINE EUROLAB is contraindicated in patients with malignant hepatic tumours (see sections 4.3 and 4.4).

Elderly

No specific dose adjustments are recommended for the elderly. AZACITIDINE EUROLAB and its metabolites are known to be substantially excreted by the kidney, and the risk of toxic reactions to

AZACITIDINE EUROLAB may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Paediatric population

The safety and efficacy of AZACITIDINE EUROLAB in children and adolescents under 18 years of age has not been established.

Laboratory tests

Liver function tests and serum creatinine should be determined prior to initiation of therapy. Complete blood counts should be performed prior to initiation of therapy and as needed to monitor response and toxicity, but at a minimum, prior to each treatment cycle.

Method of administration

AZACITIDINE EUROLAB should be administered under the supervision of a medical practitioner qualified in the use of anticancer agents.

Patients should be premedicated with anti-emetics for nausea and vomiting.

Subcutaneous administration

- Reconstituted AZACITIDINE EUROLAB should be injected subcutaneously into the upper arm, thigh or abdomen.

- Rotate sites for injection.
- New injections should be given at least 2,5 cm from an old site and never into areas where the site is tender, bruised, red or hard.

Intravenous administration

- AZACITIDINE EUROLAB solution is administered intravenously.
- Administer the total dose over a period of 10 to 40 minutes.
- The administration must be completed within 1 hour of reconstitution of the AZACITIDINE EUROLAB vial.

For instructions on reconstitution and dilution see section 6.6.

4.3 Contraindications

- AZACITIDINE EUROLAB is contra-indicated in patients with a known hypersensitivity to azacitidine or to any of the ingredients of AZACITIDINE EUROLAB (see section 6.1).
- Patients with advanced malignant hepatic tumours (see section 4.4).
- Patients must not receive live vaccines while being treated with AZACITIDINE EUROLAB.
- Pregnancy and lactation (see section 4.6).
- Children under the age of 18 years (see section 4.2).

4.4 Special warnings and precautions for use

Haematological toxicity

Treatment with AZACITIDINE EUROLAB is associated with anaemia, neutropenia and thrombocytopenia, particularly during the first 2 cycles (see section 4.8). At least prior to each treatment cycle complete blood counts should be performed as needed to monitor response and toxicity.

After administration of the recommended dosage for the first cycle, dosage for subsequent cycles should be reduced or delayed based on nadir counts and haematologic response (see section 4.2).

Patients and physicians should be advised to be observant for signs and symptoms of bleeding.

Safety and effectiveness of AZACITIDINE EUROLAB in patients with myelodysplastic syndrome (MDS) and hepatic or renal impairment have not been studied.

Hepatic impairment

Because AZACITIDINE EUROLAB is potentially hepatotoxic in patients with severe, pre-existing hepatic impairment, caution is needed in patients with liver disease. Patients with extensive tumour burden due to metastatic disease have been reported to experience progressive hepatic coma and death during AZACITIDINE EUROLAB treatment, especially in such patients with baseline albumin < 30 g/L. AZACITIDINE EUROLAB is contra-indicated in patients with advanced malignant hepatic tumours.

Renal impairment

Renal abnormalities ranging from elevated serum creatinine to renal failure and death were reported in patients treated with intravenous azacitidine, as found in AZACITIDINE EUROLAB, in combination with other chemotherapeutic agents for non-MDS conditions. In addition, renal tubular acidosis, defined as a fall in serum bicarbonate to < 20 mEq/L in association with an alkaline urine and hypokalaemia (serum potassium< 3 mEq/L) were reported in patients with Chronic myeloid leukaemia (CML) treated with azacitidine as found in AZACITIDINE EUROLAB and etoposide. If unexplained elevations of serum creatinine or BUN or reductions in serum bicarbonate (< 20 mEq/L) occur, the dosage should be reduced or held (see section 4.2).

Patients should be advised to report oliguria and anuria to their healthcare professional immediately.

Patients with renal impairment should be closely monitored for toxicity since AZACITIDINE EUROLAB and its metabolites are primarily excreted by the kidney.

Laboratory tests

Liver function tests, serum creatinine and serum bicarbonate should be determined prior to initiation of therapy and prior to each treatment cycle. Complete blood counts should be performed prior to initiation of therapy and as needed to monitor response and toxicity, but at a minimum, prior to each treatment cycle (see sections 4.2 and 4.8).

Cardiac and pulmonary disease

Safety and efficacy of AZACITIDINE EUROLAB has not been established in patients with a history of severe congestive heart failure, clinically unstable cardiac disease or pulmonary disease. It is therefore advised to exercise caution when prescribing AZACITIDINE EUROLAB to these patients. A cardiopulmonary assessment before and during the treatment should be considered.

Necrotising fasciitis

Necrotising fasciitis, including fatal cases, have been reported in patients treated with azacitidine. Treatment with AZACITIDINE EUROLAB should be discontinued in patients who develop necrotising fasciitis and appropriate treatment should be promptly initiated.

Tumour lysis syndrome

The patients at risk of tumour lysis syndrome are those with high tumour burden prior to treatment. These patients should be monitored closely, and appropriate precautions taken.

Differentiation syndrome

Cases of differentiation syndrome (also known as retinoic acid syndrome) have been reported in patients receiving injectable azacitidine as contained in AZACITIDINE EUROLAB. Differentiation syndrome may be fatal and symptoms and clinical findings include respiratory distress, pulmonary infiltrates, fever, rash, pulmonary oedema, peripheral oedema, rapid weight gain, pleural effusions, pericardial effusions, hypotension and renal dysfunction (see section 4.8). Treatment with high dose IV corticosteroids and haemodynamic monitoring should be considered at first onset of symptoms or signs suggestive of differentiation syndrome.

Temporary discontinuation of injectable azacitidine should be considered until resolution of symptoms and if resumed, caution is advised.

AZACITIDINE EUROLAB contains mannitol and may have a laxative effect.

4.5 Interactions with other medicines and other forms of interaction

Interaction studies with AZACITIDINE EUROLAB have not been conducted.

Based on *in vitro* data, azacitidine metabolism does not appear to be mediated by cytochrome P450 isoenzymes (CYPs), UDP-glucuronosyltransferases (UGTs), sulfotransferases (SULTs), and glutathione transferases (GSTs). Therefore, interactions related to these metabolising enzymes, *in vivo,* are considered unlikely.

Clinically significant inhibitory or inductive effects of azacitidine on cytochrome P450 enzymes are unlikely (see section 5.2).

4.6 Fertility, pregnancy and lactation

Women of childbearing potential / *Contraception in males and females*

Women of childbearing potential should be advised to avoid falling pregnant while taking AZACITIDINE EUROLAB.

Women of childbearing potential must use highly effective contraception during and for at least 6 months after treatment.

Men should be advised not to father a child while receiving treatment and must use effective contraception during and for at least 3 months after treatment.

Pregnancy

Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with AZACITIDINE EUROLAB. There is no adequate data on the use of AZACITIDINE EUROLAB in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown.

AZACITIDINE EUROLAB should not be used during pregnancy, if the patient becomes pregnant while taking AZACITIDINE EUROLAB, the patient should be informed of the potential hazard to the foetus.

Female partners of male patients receiving AZACITIDINE EUROLAB should note become pregnant.

Lactation

Due to the potential for tumorigenicity shown for AZACITIDINE EUROLAB in animal studies and the potential for serious adverse reactions in the nursing child, breastfeeding is contraindicated during AZACITIDINE EUROLAB therapy.

Fertility

There are no human data on the effect of azacitidine on fertility. In animals, adverse reactions with azacitidine use on male fertility have been documented. Before starting treatment, male patients should be advised to seek counselling on sperm storage.

4.7 Effects on ability to drive and use machines

Since AZACITIDINE EUROLAB may cause blurred vision and less frequently somnolence and fatigue (see section 4.8), the ability to drive and use machines may be negatively affected.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions were gastrointestinal (nausea, vomiting and diarrhoea), haematological (anaemia, thrombocytopenia, leukopenia/neutropenia), and injection site reactions.

Adverse reactions associated with intravenously administered azacitidine were similar in frequency and severity compared with subcutaneously administered azacitidine.

Tabulated summary of adverse reactions

MedDRA system organ class (SOC)	**Frequency**	**Adverse reactions**
Infections and infestations	*Frequent*	Pneumonia* (including bacterial, viral and fungal), nasopharyngitis, sepsis* (including bacterial, viral and fungal), neutropenic sepsis*, respiratory tract

		infection (includes upper and bronchitis), urinary tract infection, cellulitis, diverticulitis, oral fungal infection, sinusitis, pharyngitis, rhinitis, herpes simplex, skin infection.
	Frequency not known	Necrotising fasciitis*.
Neoplasms benign, malignant and unspecified (including cysts and polyps)	*Frequency not known*	Differentiation syndrome (*see section 4.4).*
Blood and lymphatic system disorders	*Frequent*	Febrile neutropenia*, neutropenia, leukopenia, thrombocytopenia, anaemia, pancytopenia*, bone marrow failure.
Immune system disorders	*Less frequent*	Hypersensitivity reactions.
Metabolism and nutrition disorders	*Frequent*	Anorexia, decreased appetite, hypokalaemia, dehydration.
	Less frequent	Tumour lysis syndrome.
Psychiatric disorders	*Frequent*	Insomnia, confusional state, anxiety.
Nervous system disorders	*Frequent*	Dizziness, headache, intracranial haemorrhage*,

		burning sensation, hypoesthesia, syncope, somnolence, lethargy.
	Frequency not known	Neurotoxicity.
Eye disorders	*Frequent*	Eye haemorrhage, conjunctival haemorrhage.
Cardiac disorders	*Frequent*	Pericardial effusion.
	Less frequent	Pericarditis.
Vascular disorders	*Frequent*	Hypotension*, hypertension, orthostatic hypotension, haematoma.
	Frequency not known	Blood complications.
Respiratory, thoracic and mediastinal disorders	*Frequent*	Pharyngitis, haemoptysis, nasal congestion, epistaxis, pleural effusion, dyspnoea exertional, pharyngolaryngeal pain.
	Less frequent	Interstitial lung disease.
Gastrointestinal disorders	*Frequent*	Diarrhoea, vomiting, constipation, nausea, abdominal pain (includes

		upper and abdominal discomfort), gastrointestinal haemorrhage* (includes mouth haemorrhage), haemorrhoidal haemorrhage, stomatitis, gingival bleeding, loose stools, oral mucosal petechiae, tongue ulceration, dyspepsia.
Hepato-biliary disorders	*Less frequent*	Hepatic failure*, progressive hepatic coma.
Skin and subcutaneous tissue disorders	*Frequent*	Petechiae, pruritus (includes generalized), rash, ecchymosis, purpura, alopecia, urticaria, erythema, rash macular.
	Less frequent	Acute febrile neutrophilic dermatosis, pyoderma gangrenosum.
Musculoskeletal and connective tissue disorders	*Frequent*	Arthralgia, musculoskeletal pain (includes back, bone and pain in extremity), muscle spasms, myalgia.

Renal and urinary disorders	*Frequent*	Dysuria, renal failure*, haematuria, elevated serum creatinine.
	Less frequent	Renal tubular acidosis.
General disorders and administration site conditions	*Frequent*	Pyrexia*, fatigue, asthenia, chest pain, injection site erythema, injection site pain, injection site reaction (unspecified), bruising, haematoma, induration, rash, pruritus, inflammation, discoloration, nodule and haemorrhage (at injection site), malaise, chills, catheter site haemorrhage.
	Less frequent	Injection site necrosis (at injection site).
Investigations	*Frequent*	Weight decreased.

* = rarely fatal cases have been reported

Description of selected adverse reactions

Haematologic adverse reactions

The most frequently reported haematological adverse reactions associated with azacitidine treatment include anaemia, thrombocytopenia, neutropenia and leukopenia. There is a greater risk of these events occurring during the first 2 cycles, after which they occur with less frequency in patients with restoration of haematological function. Most haematological adverse reactions were managed by routine monitoring of complete blood counts and delaying azacitidine administration in the next cycle, prophylactic antibiotics and/or growth factor support (e.g., G-CSF) for neutropenia and transfusions for anaemia or thrombocytopenia as required.

Infections

Myelosuppression may lead to neutropenia and an increased risk of infection. Serious adverse reactions such as sepsis, including neutropenic sepsis, and pneumonia were reported in patients receiving azacitidine, some with a fatal outcome. Infections may be managed with the use of anti-infectives plus growth factor support (e.g., G-CSF) for neutropenia.

Bleeding

Bleeding may occur with patients receiving azacitidine. Serious adverse reactions such as gastrointestinal haemorrhage and intracranial haemorrhage have been reported. Patients should be monitored for signs and symptoms of bleeding, particularly those with pre-existing or treatment related thrombocytopenia.

Hypersensitivity

Serious hypersensitivity reactions have been reported in patients receiving azacitidine. In case of an anaphylactic-like reaction, treatment with azacitidine should be immediately discontinued and appropriate symptomatic treatment initiated.

Skin and subcutaneous tissue adverse reactions

The majority of skin and subcutaneous adverse reactions were associated with the injection site.

The majority of adverse reactions occurred during the first 2 cycles and tended to decrease with subsequent cycles. Subcutaneous adverse reactions such as injection site rash, inflammation, pruritus, erythema and skin lesion may require management with concomitant medicinal products, such as antihistamines, corticosteroids and non-steroidal anti-inflammatory medicinal products (NSAIDs).

Gastrointestinal adverse reactions

The most frequently reported gastrointestinal adverse reactions associated with azacitidine treatment included constipation, diarrhoea, nausea and vomiting. These adverse reactions were managed symptomatically with anti-emetics for nausea and vomiting; anti-diarrhoeals for diarrhoea, and laxatives and/or stool softeners for constipation.

Renal adverse reactions

Renal abnormalities, ranging from elevated serum creatinine to renal tubular acidosis, renal failure and death were reported in patients treated with azacitidine (see section 4.4).

Hepatic adverse reactions

Patients with extensive tumour burden due to metastatic disease have been reported to experience progressive hepatic coma and death during azacitidine treatment (see section 4.4).

Cardiac events

Data from a clinical trial allowing enrolment of patients with known history of cardiovascular or pulmonary disease showed an increase in cardiac events in patients with newly diagnosed AML treated with azacitidine (see section 4.4).

Elderly population

There is limited safety information available with azacitidine in patients ≥ 85 years.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the 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.

4.9 Overdose

In the event of an overdose, side effects will be exaggerated (see section 4.8). Symptoms of overdosage may include diarrhoea, nausea and vomiting.

In the event of overdosage, the patient should be monitored with appropriate blood counts and should receive supportive treatment, as necessary. There is no known specific antidote for AZACITIDINE EUROLAB overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 26 – Cytostatic agents

Pharmacotherapeutic group: Antineoplastic agents, pyrimidine analogues

ATC code: L01BC07

Mechanism of action

Azacitidine exerts its antineoplastic effects by causing hypomethylation of DNA and direct cytotoxicity on abnormal haematopoietic cells in the bone marrow by inhibition of DNA cytosine methyltransferase. The concentration of azacitidine required for maximum inhibition of DNA methylation in vitro does not cause major suppression of DNA synthesis. Hypomethylation may restore normal function to genes that are critical for differentiation and proliferation. The cytotoxic

effects of azacitidine cause the death of rapidly dividing cells including cancer cells that are no longer responsive to normal growth control mechanisms. Non-proliferating cells are relatively insensitive to azacitidine.

5.2 Pharmacokinetic properties

Absorption

A pharmacokinetic study of azacitidine was performed by administering a single 75 mg/m^2 subcutaneous (SC) and intravenous (IV) dose.

Azacitidine was rapidly absorbed after a single 75 mg/m^2 SC dose. The peak plasma azacitidine concentration of 750 ± 403 ng/mL occurred in ½ hr. The bioavailability of SC azacitidine relative to the IV administered dose was approximately 89 % based on the AUC.

Distribution

Mean volume of distribution following IV administration was 76 ± 26 L. Mean apparent SC clearance was 167 ± 49 L/hr and mean half-life after SC administration was 41 ± 8 minutes.

Biotransformation

In vitro incubation of azacitidine in human liver fractions indicated that azacitidine may be metabolised by the liver. Whether azacitidine metabolism may be affected by known microsomal enzyme inhibitors or inducers has not been studied.

In vitro studies of azacitidine with human cultured hepatocytes indicate that azacitidine at concentrations of 1,0 µM to 100,0 µM does not induce CYP 1A2, 2C19 or 3A4/5.

Elimination

Azacitidine and its metabolites are primarily eliminated by urinary excretion. Following IV administration of radioactive azacitidine, the cumulative urinary excretion was 85 % of the radioactive dose. Faecal excretion accounted for < 1 % of administered radioactivity over three days. Mean excretion of radioactivity in urine following SC administration of 14C-azacitidine was 50 %. The mean elimination half-lives of total radioactivity (azacitidine and metabolites) were about 4 hours and were similar after IV and SC administrations.

Special populations

The effects of special populations, e.g. renal or hepatic impairment, gender, age, or race on the pharmacokinetics of azacitidine have not been studied.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol

Water for injection

6.2 Incompatibilities

This medicine must not be mixed with other medicines except those mentioned in section 6.6.

6.3 Shelf-life

24 months

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.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep out of reach of children.

For storage conditions after reconstitution and dilution of the medicine, see section 6.3.

6.5 Nature and contents of the container

A 30 mL, clear, type 1 glass vial, sealed with a grey bromo-butyl, siliconised rubber stopper and white aluminium flip-off seal.

6.6 Special precautions for disposal and other handling

Recommendations for safe handling:

AZACITIDINE EUROLAB is a cytotoxic medicine and, as with other potentially toxic compounds, caution should be exercised when handling and preparing AZACITIDINE EUROLAB suspensions. Procedures for proper handling and disposal of cytotoxic medicines should be applied.

If reconstituted AZACITIDINE EUROLAB comes into contact with the skin, immediately and thoroughly wash with soap and water. If it comes into contact with mucous membranes, flush thoroughly with water.

Preparation for the subcutaneous administration:

AZACITIDINE EUROLAB should be reconstituted aseptically with 4 mL sterile water for injection. The diluent should be injected slowly into the vial. Vigorously shake or roll the vial until a uniform suspension is achieved. The suspension will be cloudy. The resulting suspension will contain 25 mg/mL azacitidine (100 mg/4 ml).

When stored at 25 °C, the reconstituted product should be administered within 1 hour. Doses greater than 4 mL should be divided equally into two syringes and injected into two separate sites. To provide a homogeneous suspension, the contents of the syringe must be re-suspended by inverting the syringe 2 – 3 times and vigorously rolling the syringe between the palms for 30 seconds immediately prior to administration.

Preparation for the intravenous administration:

Reconstitute the appropriate number of AZACITIDINE EUROLAB vials to achieve the desired dose as follows.

Reconstitute each vial with 10 mL sterile water for injection. Vigorously shake or roll the vial until all solids are dissolved. The resulting solution will contain azacitidine 10 mg/mL. The solution should be clear. Do not filter the solution as this could remove any undissolved active substance.

Withdraw the required amount of AZACITIDINE EUROLAB solution to deliver the desired dose and inject into a 50 - 100 mL infusion bag of either 0,9 % Sodium Chloride Injection or Lactated Ringer's Injection.

Preparation for delayed administration:

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.

Disposal: Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Eurolab (Pty) Ltd.

3 Stirrup Lane,

Woodmead Office Park,

Van Reenens Avenue,

Woodmead,

Gauteng, South Africa

8. REGISTRATION NUMBER

51/26/0452

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

17 November 2020

10. DATE OF REVISION OF THE TEXT

28 July 2026