APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

Diclofenac 50 Unicorn film-coated tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Diclofenac 50 Unicorn film-coated tablets.

Each film-coated tablet contains 50 mg diclofenac potassium.

Contains sugar: lactose monohydrate (95 mg/tablet).

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-Coated Tablets

Diclofenac 50 Unicorn film-coated tablets.

Reddish brown, round, biconvex, film–coated tablets debossed with ‘DP’ on one side and ‘50’ on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Diclofenac 50 Unicorn is indicated for a maximum period of 5 days when intended for the emergency treatment of acute gout attacks.

4.2 Posology and method of administration

Posology:

Use the lowest effective dose for the shortest possible duration of treatment.

Adults:

Initial daily dose: 100 to 150 mg in two to three divided doses, with a maximum daily dose of 150 mg in divided doses.

4.3 Contraindications

- Hypersensitivity to diclofenac or to any of the excipients of Diclofenac 50 Unicorn listed in section 6.1.
- Hypersensitivity to other NSAIDs, including acetylsalicylic acid (aspirin).
- Active, gastric or intestinal ulcer, bleeding or perforation.
- History of gastrointestinal bleeding or perforation (PUB) related to previous NSAID therapy.
- Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac is also contraindicated in patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs.
- Pregnancy and lactation (see section 4.6).
- Porphyria.
- Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
- Hepatic failure.
- Renal failure.

4.4 Special warnings and precautions for use

General

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.2).

The concomitant use of Diclofenac 50 Unicorn with systemic NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects (see section 4.5).

Caution is indicated in the elderly on basic medical grounds. In particular, it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight (see section 4.2).

As with other nonsteroidal anti-inflammatory drugs including Diclofenac 50 Unicorn, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug (see section 4.8). Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to diclofenac.

Diclofenac 50 Unicorn may mask the signs and symptoms of the infection due to its pharmacodynamic properties.

Gastrointestinal effects:

Gastrointestinal bleeding (haematemesis, melaena) ulceration or perforation which can be fatal has been reported with all NSAIDs including Diclofenac 50 Unicorn and may occur at any time during treatment, with or without warning symptoms or a previous history of serious GI events. They generally have more serious consequences in the elderly. If gastrointestinal bleeding or ulceration occurs in patients receiving Diclofenac 50 Unicorn, the medicine should be withdrawn.

Close medical observation is imperative and particular caution should be exercised when prescribing Diclofenac 50 Unicorn in patients with symptoms indicative of gastrointestinal disorders, or with a history suggestive of gastric or intestinal ulceration, bleeding or perforation (see section 4.8). The risk of GI bleeding, ulceration or perforation is higher with

increasing NSAID doses including Diclofenac 50 Unicorn, and in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation.

The elderly have increased frequency of adverse reactions to NSAIDs especially gastro intestinal bleeding and perforation which may be fatal (see section 4.2).

To reduce the risk of GI toxicity in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly, the treatment should be initiated and maintained at the lowest effective dose.

Combination therapy with protective medicines (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant use of medicines containing low dose acetylsalicylic acid (aspirin) or medicines likely to increase gastrointestinal risk (see section 4.5).

Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding).

Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRIs) or anti-platelet medicines such as acetylsalicylic acid (see section 4.5).

Close medical surveillance and caution should be exercised in patients with ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, and/or angiodysplasia as these conditions may be exacerbated (see section 4.8).

NSAIDs, including diclofenac, may be associated with increased risk of gastro-intestinal anastomotic leak. Close medical surveillance and caution are recommended when using Diclofenac 50 Unicorn after gastro-intestinal surgery.

Hepatic effects:

Close medical surveillance is required when prescribing Diclofenac 50 Unicorn to patients with impairment of hepatic function as their condition may be exacerbated.

Diclofenac 50 Unicorn may increase values of one or more liver enzymes. During prolonged treatment with Diclofenac 50 Unicorn, regular monitoring of hepatic function is indicated as a precautionary measure.

If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), Diclofenac 50 Unicorn should be discontinued.

Hepatitis may occur with Diclofenac 50 Unicorn without prodromal symptoms.

Caution is called for when using Diclofenac 50 Unicorn in patients with hepatic porphyria, since it may trigger an attack.

Renal effects:

As fluid retention and oedema have been reported in association with NSAIDs therapy, including Diclofenac 50 Unicorn, particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicines that can significantly impact renal function, and those patients with substantial extracellular volume depletion from any cause, e.g. before or after major surgery (see section 4.3). Monitoring of renal function is recommended as a precautionary measure when using Diclofenac 50 Unicorn in such cases. Discontinuation therapy is usually followed by recovery to the pre-treatment state.

Skin effects:

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with the use of NSAIDs, including Diclofenac 50 Unicorn (see section 4.8). Patients appear to be at the highest risk of these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment. Diclofenac 50 Unicorn should be discontinued at the first appearance of skin rash, mucosal lesions or any other signs of hypersensitivity.

SLE and mixed connective tissue disease:

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis (see section 4.8).

Cardiovascular and cerebrovascular effects:

Patients with congestive heart failure (NYHA-I) or patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with Diclofenac 50 Unicorn after careful consideration.

As the cardiovascular risks of Diclofenac 50 Unicorn may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.

Appropriate monitoring and advice are required for patients with a history of hypertension and congestive heart failure (NYHA-I) as fluid retention and oedema have been reported in association with NSAID therapy, including Diclofenac 50 Unicorn.

Clinical trial and epidemiological data consistently point towards increased risk of arterial thrombotic events (for example myocardial infarction or stroke) associated with the use of diclofenac as in Diclofenac 50 Unicorn, particularly at high dose (150mg daily) and in long term treatment.

Patients should remain alert for the signs and symptoms of serious arteriothrombotic events (e.g. chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a medical practitioner immediately in case of such an event.

Haematological effects:

Use of Diclofenac 50 Unicorn tablets 50mg are recommended only for short term treatment.

During prolonged treatment with Diclofenac 50 Unicorn, as with other NSAIDs, monitoring of the blood count is recommended.

Diclofenac 50 Unicorn may reversibly inhibit platelet aggregation (see anticoagulants in section 4.5). Patients with defects of haemostasis, bleeding diathesis or haematological abnormalities should be carefully monitored.

Pre-existing asthma:

In patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (i.e. nasal polyps), chronic obstructive pulmonary diseases or chronic infections of the respiratory tract (especially if linked to allergic rhinitis-like symptoms), reactions on NSAIDs as in Diclofenac 50 Unicorn like asthma exacerbations (so called intolerance to analgesics / analgesics asthma), Quincke's oedema or urticaria are more frequent than in other patients. Therefore, special precaution is recommended in such patients (readiness for emergency). This is applicable as well for patients who are allergic to other substances, e.g. with skin reactions, pruritus or urticaria.

Like other medicines that inhibit prostaglandin synthetase activity, Diclofenac 50 Unicorn and other NSAIDs can precipitate bronchospasm if administered to patients suffering from, or with a previous history of bronchial asthma.

Female fertility:

The use of Diclofenac 50 Unicorn may impair female fertility and is not recommended in women attempting to conceive. In women who may have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Diclofenac 50 Unicorn should be considered (see section 4.6).

Lactose

Diclofenac 50 Unicorn contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Sodium

Diclofenac 50 Unicorn contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicines and other forms of interaction

Lithium:

If used concomitantly, Diclofenac 50 Unicorn may increase plasma concentrations of lithium. Monitoring of the serum lithium level is recommended.

Digoxin:

If used concomitantly, Diclofenac 50 Unicorn may raise plasma concentrations of digoxin. Monitoring of the serum digoxin level is recommended.

Diuretics and antihypertensive medicines:

Concomitant use of Diclofenac 50 Unicorn with diuretics and antihypertensive medicines (e.g. beta-blockers, angiotensin converting enzyme (ACE) inhibitors may cause a decrease in their antihypertensive effect via inhibition of vasodilatory prostaglandin synthesis. Therefore, the combination should be administered with caution and patients, especially the elderly, should have their blood pressure periodically monitored. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy periodically thereafter, particularly for diuretics and ACE inhibitors due to the increased risk of nephrotoxicity (see section 4.4).

Medicines known to cause hyperkalaemia:

Concomitant treatment with potassium-sparing diuretics, ciclosporin, tacrolimus or trimethoprim may be associated with increased serum potassium levels, which should therefore be monitored frequently (see section 4.4).

Anticoagulants and anti-platelet medicines:

Caution is recommended since concomitant administration could increase the risk of bleeding (see section 4.4). Although clinical investigations do not appear to indicate that diclofenac as in Diclofenac 50 Unicorn has an influence on the effect of anticoagulants (such as warfarin), there are reports of an increased risk of haemorrhage in patients receiving diclofenac and anticoagulant concomitantly (see section 4.4). Therefore, to be certain that no change in anticoagulant dosage is required, close monitoring of such patients is required. Diclofenac 50 Unicorn in a high dose can reversibly inhibit platelet aggregation.

Other NSAIDs including cyclooxygenase-2 selective inhibitors and corticosteroids:

Co-administration of Diclofenac 50 Unicorn with other systemic NSAIDs or corticosteroids may increase the risk of gastrointestinal bleeding or ulceration. Avoid concomitant use of two or more NSAIDs (see section 4.4).

Selective serotonin reuptake inhibitors (SSRIs):

Concomitant administration of SSRI's may increase the risk of gastrointestinal bleeding (see section 4.4).

Antidiabetics:

Clinical studies have shown that diclofenac as in Diclofenac 50 Unicorn can be given together with oral antidiabetic medicines without influencing their clinical effect. However there have been isolated reports of hypoglycaemic and hyperglycaemic effects necessitating changes in the dosage of the antidiabetic medicines during treatment with

diclofenac. For this reason, monitoring of the blood glucose level is recommended as a precautionary measure during concomitant therapy.

Methotrexate:

Diclofenac 50 Unicorn can inhibit the tubular renal clearance of methotrexate hereby increasing methotrexate levels.

Caution is recommended when NSAIDs, including Diclofenac 50 Unicorn, are administered less than 24 hours before treatment with methotrexate, since blood concentrations of methotrexate may rise and the toxicity of this substance be increase. Cases of serious toxicity have been reported when methotrexate and NSAIDs, including Diclofenac 50 Unicorn are given within 24 hours of each other. This interaction is mediated through accumulation of methotrexate resulting from impairment of renal excretion in the presence of the NSAID.

Ciclosporin:

Diclofenac 50 Unicorn, may increase the nephrotoxicity of ciclosporin due to the effect on renal prostaglandins. Therefore, it should be given at doses lower than those that would be used in patients not receiving ciclosporin.

Tacrolimus:

Possible increased risk of nephrotoxicity when NSAIDs as in Diclofenac 50 Unicorn are given with tacrolimus. This might be mediated through renal antiprostaglandin effects of both NSAID and calcineurin inhibitor.

Quinolone antibacterials:

Convulsions may occur due to an interaction between quinolones and NSAIDs as in Diclofenac 50 Unicorn. This may occur in patients with or without a previous history of

epilepsy or convulsions. Therefore, caution should be exercised when considering the use of a quinolone in patients who are already receiving an NSAID.

Phenytoin:

When using phenytoin concomitantly with Diclofenac 50 Unicorn, monitoring of phenytoin plasma concentrations is recommended due to an expected increase in exposure to phenytoin.

Colestipol and cholestyramine:

These medicines can induce a delay or decrease in absorption of Diclofenac 50 Unicorn. Therefore, it is recommended to administer Diclofenac 50 Unicorn at least one hour before or 4 to 6 hours after administration of colestipol/ cholestyramine.

Cardiac glycosides:

Concomitant use of cardiac glycosides and NSAIDs as in Diclofenac 50 Unicorn in patients may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Mifepristone:

NSAIDs as in Diclofenac 50 Unicorn should not be used for 8 - 12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Potent CYP2C9 inhibitors:

Caution is recommended when co-prescribing Diclofenac 50 Unicorn with potent CYP2C9 inhibitors (such as voriconazole), which could result in a significant increase in peak plasma concentrations and exposure to Diclofenac 50 Unicorn due to inhibition of Diclofenac 50 Unicorn metabolism.

4.6 Fertility, pregnancy and lactation

Safety and efficacy in pregnancy and lactation have not been established.

Pregnancy

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and or cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy.

The risk is believed to increase with dose and duration of therapy.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension).
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis.

The mother and the neonate, at the end of the pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, Diclofenac 50 Unicorn is contraindicated during the third trimester of pregnancy (see section 4.3).

Breastfeeding

Like other NSAIDs, diclofenac as in Diclofenac 50 Unicorn passes into breast milk in small amounts. Therefore Diclofenac 50 Unicorn should not be administered during breast feeding in order to avoid undesirable effects in the infant (see section 5.2).

Female fertility

The use of Diclofenac 50 Unicorn may impair female fertility and is not recommended in women attempting to conceive.

4.7 Effects on ability to drive and use machines

Patients who experience visual disturbances, dizziness, vertigo, somnolence, central nervous system disturbances, drowsiness, or fatigue while taking Diclofenac 50 Unicorn should refrain from driving or operating machinery.

4.8 Undesirable effects

Tabulated summary of adverse reactions

MedDRA system organ class	**Frequency**	**Adverse reactions**
Blood and the lymphatic system disorders	Less frequent	Thrombocytopenia, leucopenia, anaemia (including haemolytic and aplastic anaemia), agranulocytosis
Immune system disorders	Less frequent	Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), angioedema (including face oedema)
Psychiatric disorders	Less frequent	Disorientation, depression, insomnia, nightmare, irritability, psychotic disorder
Nervous system disorders	Frequent	Headache, dizziness, nervousness
	Less frequent	Somnolence, tiredness, paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident
	Frequency unknown	Confusion, hallucinations, disturbances of sensation, malaise
Eye disorders	Less frequent	Visual disturbance, vision blurred diplopia

MedDRA system organ class	**Frequency**	**Adverse reactions**
	Frequency unknown	Optic neuritis
Ear and labyrinth disorders	Less frequent	Vertigo
	Frequency unknown	Tinnitus, hearing impaired
Cardiac disorders	Less frequent	Myocardial infarction, cardiac failure, palpitations, chest pain, oedema
	Frequency unknown	Kounis syndrome
Vascular disorders	Less frequent	Hypertension, hypotension, vasculitis
Respiratory, thoracic and mediastinal disorders:	Less frequent	Asthma (including dyspnoea), pneumonitis
Gastrointestinal disorders:	Frequent	Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, eructation
	Less frequent	Gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, melaena, gastrointestinal ulcer with or without bleeding or perforation (sometimes fatal particularly in the elderly), colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, aphthous stomatitis, glossitis, oesophageal disorder, diaphragm-like

MedDRA system organ class	**Frequency**	**Adverse reactions**
		intestinal strictures, pancreatitis, alteration in taste
	Frequency unknown	Ischaemic colitis, ulcerative stomatitis, gastritis
Hepatobiliary disorders	Frequent	Transaminases increased (ALT, AST)
	Less frequent	Hepatitis, jaundice, liver disorder, fulminant hepatitis, hepatic necrosis, hepatic failure
Skin and subcutaneous tissue disorders:	Frequent	Rash or other skin reactions
	Less frequent	Urticaria, bullous eruptions, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, pruritus
Renal and urinary disorders:	Less frequent	Acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis
Reproductive system and breast disorders	Less frequent	Impotence

Description of selected adverse reactions

Due to its pharmacodynamic properties Diclofenac 50 Unicorn may mask signs and symptoms of infection.

Gastric bleeding may occur at any time during treatment with Diclofenac 50 Unicorn.

Discontinue treatment immediately.

Heart failure may be precipitated in some compromised patients due to the

inherent potential of Diclofenac 50 Unicorn to cause fluid retention.

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Symptoms

Over dosage can cause symptoms such as headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, diarrhoea, dizziness, disorientation, excitation, coma, drowsiness, tinnitus, fainting or convulsions. In the case of significant poisoning acute renal failure and liver damage are possible.

Management

Management of acute poisoning with NSAIDs, including Diclofenac 50 Unicorn, essentially consists of supportive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression.

Special measures such as forced diuresis, dialysis or haemo-perfusion are probably of no help in eliminating NSAIDs, including Diclofenac 50 Unicorn, due to high protein binding and extensive metabolism.

Activated charcoal may be considered after ingestion of a potentially toxic overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A.3.1. Antirheumatics (anti-inflammatory agents)

Pharmacotherapeutic group: antiinflammatory and antirheumatic products, non-steroids,

ATC code: M01AB05

Diclofenac is a non-steroidal anti-inflammatory compound (NSAID) with analgesic, antipyretic and anti-inflammatory activities. It causes decreased formation of prostaglandins and thromboxanes through inhibition of the activity of the enzyme cyclo-oxygenase. Prostaglandins play a major role in the aetiology of inflammation, pain and fever and the inhibition of prostaglandin synthesis may have an important bearing on diclofenac's mechanism of action. Diclofenac inhibits platelet aggregation *in vitro.*

5.2 Pharmacokinetic properties

Absorption

Diclofenac is well absorbed after oral administration. Peak plasma concentrations are reached within approximately 1 hour. Administration with food slows the rate but does not alter the extent of absorption.

Distribution:

There is a substantial first-pass effect (only 50 % of diclofenac is available systemically). Diclofenac is extensively bound to plasma proteins (99 %) and its plasma half-life is 1 to 2 hours.

Biotransformation:

Diclofenac is metabolised in the liver by a cytochrome P450 isozyme of the CYP2C subfamily.

Elimination:

Diclofenac Is excreted In the form of metabolites via the kidneys (approximately 60 %) and faeces (approximately 30 %). Less than 1 % is excreted in unchanged form.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Lactose monohydrate

Microcrystalline cellulose

Croscarmellose sodium

Sodium Lauryl sulphate

Colloidal silicon dioxide

Magnesium stearate

Tablet coating:

Instacoat Universal Brown:

Hypromellose (E464)

Talc (E553b)

Titanium dioxide (E171)

Red iron oxide (E172)

Yellow iron oxide (E172)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30 °C in the original packaging.

6.5 Nature and contents of container

Blister pack of 9 (1 x 9's) film-coated tablets.

- Blister card: Alum pack-GDO cold forming base foil and lidding foil zeon 25µ foil 7gsm HSL-DSO).
- Blister card: PVDC coated rigid PE/PVC laminate as base foil and lidding foil zeon 25µ foil 7gsm HSLDSO).

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

Cnr. Searle & Pontac Streets

Cape Town, 8001

South Africa

8. REGISTRATION NUMBER

56/3.1/0559

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05 September 2023

10. DATE OF REVISION OF THE TEXT

05 September 2023