Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

SHALCIP-TZ (Ciprofloxacin Hydrochloride and Tinidazole Tablets)

2. Qualitative and quantitative composition

Ciprofloxacin Hydrochloride USP 500mg & Tinidazole BP 600mg

3. Pharmaceutical form

Tablet (Oral)
Yellow coloured, capsule shaped, film coated tablets having central break line on one side and plain on other side.

4. Clinical particulars

4.1 Therapeutic indications

Shalcip TZ is indicated for the treatment of a wide variety of infections caused by susceptible gram- positive and gram-negative organisms along with anaerobes and protozoa. Surgical prophylaxis and surgical wound infections, Gynaecological infections including prophylaxis in gynaecological surgeries, Respiratory Tract infections like lung abscess, aspiration pneumonia, empyema and bronchiectasis, ENT infections like chronic sinusitis, chronic suppurative otitis media, cholesteatoma and mastoiditis, Orofacial and Dental infections, Dermatological infections like cellulitis, breast and other cutaneous abscesses, gangrene, diabetic and decubitus ulcers, Intra-abdominal infections and diarrhoeas of mixed bacterial and protozoal origin.

4.2 Posology and method of administration

Shalcip TZ should be taken one hour before or two hours after meals with a glass of water. Adults: One tablet twice a day. In Impaired Renal Function - If creatinine clearance is less than 20ml/min, half the recommended dosage may be administered.
Route of administration: Oral

4.3 Contraindications

Hypersensitivity to the quinolone group or the nitroimidazole group of compounds and those patients with a history of blood dyscrasias.

4.4 Special warnings and precautions for use

Usage in Pregnancy & Lactation: Shalcip TZ is not recommended for use

in pregnancy.
Nursing Mothers: Shalcip TZ is not recommended for use in nursing mothers.
Paediatric Use: As with other drugs of this class, ciprofloxacin has been shown to cause arthropathy in weightbearing joints of immature animals. Hence ciprofloxacin is usually not recommended for use in children. Seizures and neuropathy have been reported with tinidazole, discontinue drug if abnormal neurologic signs develop, Vaginal candidiasis may develop with tinidazole and require treatment with an antifungal agent. Use tinidazole with caution in patients with blood dyscrasias, tinidazole may produce transient leukopenia and neutropenia.
The drug may cause low blood sugar and mental health related side effects. Low blood sugar levels, also called hypoglycaemia, can lead to coma. The mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects of the fluoroquinolones are: Disturbances in attention. Disorientation. Agitation. Nervousness. Memory Impairment. Serious disturbances in mental abilities called delirium. This drug may cause low blood sugar and mental health related side effects.
Fluoroquinolones have the potential to cause permanent peripheral neuropathy.

4.5 Interaction with other medicinal products and other forms of interaction

Theophylline: Serum concentration and elimination half-life of theophylline may be increased when it is used concurrently with ciprofloxacin. Antacids containing magnesium hydroxide and/or aluminium hydroxide may interfere with the absorption of ciprofloxacin, resulting in lower serum and urine levels. Anticoagulants: Prolongation of bleeding time has been reported during concomitant administration of ciprofloxacin and anticoagulants. Cyclosporin: Transient increases
in serum creatinine have been seen following concomitant administration of cyclosporin and ciprofloxacin. Caffeine: Ciprofloxacin may interfere with the metabolism of caffeine resulting in reduced clearance of caffeine. Alcohol: Disulfiram like antabuse reaction may occur due to Tinidazole.

4.6 Pregnancy and Lactation

Usage in Pregnancy & Lactation: Shalcip TZ is not recommended
Pregnancy
The data that are available on administration of ciprofloxacin to pregnant women indicates no malformative or feto/neonatal toxicity of ciprofloxacin. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. In juvenile and prenatal animals exposed to quinolones, effects on immature cartilage have been observed, thus, it cannot be excluded that the drug could cause damage to articular cartilage in the human immature organism / foetus (see section 5.3).

As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy.

Breast-feeding

Ciprofloxacin is excreted in breast milk. Due to the potential risk of articular damage, ciprofloxacin should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

CNS stimulation: Ciprofloxacin should be used with caution in patients with CNS disorders such as severe cerebral arteriosclerosis or epilepsy. Crystalluria: Inadequate intake of water, when on ciprofloxacin, can cause crystalluria. Phototoxicity: Moderate to severe phototoxicity has been observed in patients who are exposed to direct sunlight with some members of the quinolone class of drugs. Metallic taste, mild nausea, headache, vomiting, anorexia, abdominal pain, furry tongue,

pruritus, photosensitivity, vasculitis, skin rash, dizziness, vertigo, incoordination, insomnia, tremor, convulsion, paraesthesia, blurred vision, eosinophilia, leucopenia, myalgia, tendinitis and exacerbation of myasthenia gravis.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

In the event of acute overdosage, reversible renal toxicity has been reported in some cases. The stomach should be emptied by inducing vomiting or by gastric lavage. The patient should be carefully observed and given supportive treatment, including monitoring of renal function and administration of magnesium, aluminum, or calcium containing antacids which can reduce the absorption of ciprofloxacin. Adequate hydration must be maintained. Only a small amount of ciprofloxacin (< 10%) is removed from the body after hemodialysis or peritoneal dialysis. There is no specific antidote for the treatment of overdosage with tinidazole; therefore, treatment should be symptomatic and supportive. Gastric lavage may be helpful. Hemodialysis can be considered because approximately 43% of the amount present in the body is eliminated during a 6-hour hemodialysis session.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Shalcip TZ Tablets is a fixed dose combination of ciprofloxacin hydrochloride and tinidazole. Ciprofloxacin is a fluorinated 4-quinolone anti-bacterial agent with a broad spectrum of activity. Tinidazole is a nitroimidazole which has antimicrobial action against microaerophilic Protozoa, Giardia lamblia, Entamoeba histolytica and Trichomonas vaginalis and against obligate anaerobic bacteria.
ATC Code: J01MA02 – Ciprofloxacin Hydrochloride and J01XD02 – Tinidazole
Mechanism of action
Ciprofloxacin exerts its bactericidal effect by inhibiting the A subunit of DNA gyrase, an essential enzyme involved in DNA replication. Tinidazole acts by damage of DNA strands or inhibition of their synthesis.

5.2 Pharmacokinetic properties

The absorption of Omeprazole is fast and 30-40% of the medicine enters into blood circulation.
The peak concentration in the plasma (fluid part of blood) is reached within 0.5 to 3.5 hours after the dose of 40 mg.
Domperidone is rapidly absorbed, with the peak plasma concentration is reached in approximately 1 hour after oral administration. It is altered chemically in the liver and eliminated from the body in the urine and faeces at 31% and 66% of the oral dose, respectively.

5.3 Preclinical safety data

Non-clinical data reveal no special hazards for humans based on conventional studies of single dose toxicity, repeated dose toxicity, carcinogenic potential, or toxicity to reproduction.

Like a number of other quinolones, ciprofloxacin is phototoxic in animals at clinically relevant exposure levels. Data on photomutagenicity/photocarcinogenicity show a weak photomutagenic or phototumorigenic effect of ciprofloxacin in-vitro and in animal experiments. This effect was comparable to that of other gyrase inhibitors.

Articular tolerability:

As reported for other gyrase inhibitors, ciprofloxacin causes damage to the large weight-bearing joints in immature animals. The extent of the cartilage damage varies according to age, species and dose; the damage can be reduced by taking the weight off the joints. Studies with mature animals (rat, dog) revealed no evidence of cartilage lesions. In a study in young beagle dogs, ciprofloxacin caused severe articular changes at therapeutic

doses after two weeks of treatment, which were still observed after 5 months.

6. Pharmaceutical Particulars

6.1 List of Excipients

Calcium Hydrogen Phosphate BP,
Maize Starch BP,
Methyl Hydroxybenzoate BP,
Propyl Hydroxybenzoate BP,
Magnesium Stearate BP,
Colloidal Anhydrous Silica BP,
Croscarmellose Sodium BP,
Sodium Starch Glycolate BP,
Hypromellose BP,
Lactose BP,
Polyethylene Glycol BP,
Purified Talc BP

6.2 Incompatibilities

Not Applicable.

6.3 Shelf-Life

36 months (3 Years)

6.4 Special Precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and Content of container

Shalcip TZ is available in a blister pack of 10 tablets. 1 such filled blister packed in carton along with a leaflet. 10 such inner cartons are packed in outer carton.

6.6 Special precautions for disposal and other handling

No special requirement

7. Marketing Authorization Holder

SHALINA HEALTHCARE DMCC

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

8. Marketing Authorization Number
H2014/CTD1007/241/R1

9. Date of first authorization/renewal of the authorization
September 15, 2025

10. Date of revision of the text
September 15, 2025