SUMMARY OF CHARACTERISTICS OF PRODUCTS

1. NAME OF THE MEDICINAL PRODUCT

SHALCIP-TZ (Ciprofloxacin Hydrochloride and Tinidazole Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr.No.	Approved Name (if any)	Quantity per dosage unit in mg
1.	Ciprofloxacin Hydrochloride USP	582.200
2.	Tinidazole BP	600.000
3.	Dibasic Calcium Phosphate (DCP) BP	67.340
4.	Sodium Starch Glycolate BP	15.000
5.	Maize Starch (For Paste) BP	19.000
6.	Methyl Hydroxy benzoate BP	1.330
7.	Propyl Hydroxy benzoate BP	0.130
8.	Croscarmellose Sodium BP	15.000
9.	Colloidal Anhydrous Silica (Aerosil) BP	5.000
10.	Magnesium Stearate BP	15.000
11.	Instacoat Aqua IA-III- 40130 Yellow	12.000

Ciprofloxacin Hydrochloride 582.20 mg = Ciprofloxacin anhydrous 500 mg.

Definitions:

BP: British Pharmacopoeia

USP : United States of Pharmacopoeia

IH: In-house Specification

3. PHARMACEUTICAL FORM

Tablets (Oral)

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.

4.3 Contraindications

Hypersensitivity to the quinolone group or the nitroimidazole group of compounds and the 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: Disulfiramlike antabuse reaction may occur due to Tinidazole.

4.6 Pregnancy and lactation

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.

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

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

Not Applicable

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 contents 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

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

7. MARKETING AUTHORISATION HOLDER

Shalina Healthcare Nigeria Limited

8. DATE OF UPDATE OF TEXT

Every two years.