AZITHROMYCIN TABLETS 250 mg

Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

AZITHROMYCIN TABLETS 250 MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Film Coated Tablet contains
Azithromycin Dihydrate USP
Eq. to Azithromycin 250 mg
Excipients Q.S.
For excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Pinkish Brown coloured, capsule shaped Biconvex Film coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acute Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease due to Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.

Acute Bacterial Sinusitis due to Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.

Community-Acquired Pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae or Streptococcus pneumoniae in patients appropriate for oral therapy.

NOTE: Azithromycin should not be used in patients with pneumonia who are judged to be inappropriate for oral therapy because of moderate to severe illness or risk factors such as any of the following:

- patients with cystic fibrosis,
- patients with nosocomially acquired infections,
- patients with known or suspected bacteremia,
- patients requiring hospitalization,
- elderly or debilitated patients, or

- patients with significant underlying health problems that may compromise their ability to respond to their illness (including immunodeficiency or functional asplenia).

Pharyngitis/Tonsillitis caused by Streptococcus pyogenes as an alternative to first-line therapy in individuals who cannot use first-line therapy.

NOTE: Penicillin by the intramuscular route is the usual drug of choice in the treatment of Streptococcus pyogenes infection and the prophylaxis of rheumatic fever. Azithromycin tablets are often effective in the eradication of susceptible strains of Streptococcus pyogenes from the nasopharynx. Because some strains are resistant to Azithromycin tablets, susceptibility tests should be performed when patients are treated with Azithromycin tablets. Data establishing efficacy of Azithromycin in subsequent prevention of rheumatic fever are not available.

Uncomplicated Skin and Skin Structure Infections due to Staphylococcus aureus, Streptococcus pyogenes, or Streptococcus agalactiae. Abscesses usually require surgical drainage.

Urethritis and Cervicitis due to Chlamydia trachomatis or Neisseria gonorrhoeae.

Genital Ulcer Disease in men due to Haemophilus ducreyi (chancroid). Due to the small number of women included in clinical trials, the efficacy of Azithromycin in the treatment of chancroid in women has not been established.

Azithromycin tablets, at the recommended dose, should not be relied upon to treat syphilis. Antimicrobial agents used in high doses for short periods of time to treat non-gonococcal urethritis may mask or delay the symptoms of incubating syphilis. All patients with sexually-transmitted urethritis or cervicitis should have a serologic test for syphilis and appropriate cultures for gonorrhea performed at the time of diagnosis. Appropriate antimicrobial therapy and follow-up tests for these diseases should be initiated if infection is confirmed.

Appropriate culture and susceptibility tests should be performed before treatment to determine the causative organism and its susceptibility to Azithromycin. Therapy with Azithromycin tablets may be initiated before results of these tests are known; once the results become available, antimicrobial therapy should be adjusted accordingly.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Azithromycin tablets and other antibacterial drugs, Azithromycin tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Pediatric Patients

Acute Otitis Media caused by Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.

Community-Acquired Pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae or Streptococcus pneumoniae in patients appropriate for oral therapy.

NOTE: Azithromycin should not be used in pediatric patients with pneumonia who are judged to be inappropriate for oral therapy because of moderate to severe illness or risk factors such as any of the following:

- patients with cystic fibrosis,
- patients with nosocomially acquired infections,
- patients with known or suspected bacteremia,
- patients requiring hospitalization, or
- patients with significant underlying health problems that may compromise their ability to respond to their illness (including immunodeficiency or functional asplenia).

Pharyngitis/Tonsillitis caused by Streptococcus pyogenes as an alternative to first-line therapy in individuals who cannot use first-line therapy.

NOTE: Penicillin by the intramuscular route is the usual drug of choice in the treatment of Streptococcus pyogenes infection and the prophylaxis of rheumatic fever. Azithromycin tablets are often effective in the eradication of susceptible strains of Streptococcus pyogenes from the nasopharynx. Because some strains are resistant to Azithromycin tablets, susceptibility tests should be performed when patients are treated with Azithromycin tablets. Data establishing efficacy of Azithromycin in subsequent prevention of rheumatic fever are not available.

Appropriate culture and susceptibility tests should be performed before treatment to determine the causative organism and its susceptibility to Azithromycin. Therapy with Azithromycin tablets may be initiated before results of these tests are known; once the results become available, antimicrobial therapy should be adjusted accordingly.

4.2. Posology and method of administration

Posology

Adults

In uncomplicated Chlamydia trachomatis urethritis and cervicitis the dose is 1000 mg as a single oral dose.

For all other indications the dose is 1500 mg, to be administered as 500 mg per day for three consecutive days. As an alternative the same total dose (1500 mg) can also be administered over a period of five days with 500 mg on the first day and 250 mg on the second to the fifth day.

Elderly people

The same dose as in adult patients is used for older people. Since elderly people can be patients with ongoing proarrhythmic conditions a particular caution is recommended due to the risk of developing cardiac arrhythmia and torsades de pointes (see section 4.4).

Paediatric population

Azithromycin tablets should only be administered to children weighing more than 45 kg when normal adult dose should be used. For children under 45 kg other pharmaceutical forms of azithromycine, e.g. suspensions, may be used.

In patients with renal impairment: No dose adjustment is necessary in patients with mild to moderate renal impairment (GFR 10-80 ml/min) (see section 4.4).

In patients with hepatic impairment: A dose adjustment is not necessary for patients with mild to moderately impaired liver function (see section 4.4).

Method of administration

Azithromycin Tablets should be given as a single daily dose. The tablets may be taken with food.

4.3. Contra-indications

Azithromycin tablets are contraindicated in patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic.

4.4. Special warnings and special precautions for use

Serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens Johnson Syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy. Although rare, fatalities have been reported. Despite initially successful symptomatic treatment of the allergic symptoms, when symptomatic therapy was discontinued, the allergic symptoms recurred soon thereafter in some patients without further azithromycin exposure. These patients required prolonged periods of observation and symptomatic treatment. The relationship of these episodes to the long tissue half-life of azithromycin and subsequent prolonged exposure to antigen is unknown at present.

If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

In the treatment of pneumonia, azithromycin has only been shown to be safe and effective in the treatment of community-acquired pneumonia due to ***Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae*** or ***Streptococcus pneumoniae*** in patients appropriate for oral therapy. Azithromycin should not be used in patients with pneumonia who are judged to be inappropriate for oral therapy because of moderate to severe illness or risk factors such as any of the following: patients with cystic fibrosis, patients with nosocomially acquired infections, patients with known or suspected bacteremia, patients requiring hospitalization, elderly or debilitated

patients, or patients with significant underlying health problems that may compromise their ability to respond to their illness (including immunodeficiency or functional asplenia).

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including azithromycin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS

General

Because azithromycin is principally eliminated via the liver, caution should be exercised when azithromycin is administered to patients with impaired hepatic function. Due to the limited data in subjects with GFR <10 mL/min, caution should be exercised when prescribing azithromycin in these patients.

Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and *torsades de pointes*, have been seen in treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarization.

Prescribing azithromycin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

4.5. Interactions with other medicinal products and other forms of interaction

Co-administration of nelfinavir at steady-state with a single oral dose of azithromycin resulted in increased azithromycin serum concentrations. Although a dose adjustment of azithromycin is not recommended when administered in combination with nelfinavir, close monitoring for known side effects of azithromycin, such as liver enzyme abnormalities and hearing impairment, is warranted.

Azithromycin did not affect the prothrombin time response to a single dose of warfarin. However, prudent medical practice dictates careful monitoring of prothrombin time in all patients treated with azithromycin and warfarin concomitantly. Concurrent use of macrolides and warfarin in clinical practice has been associated with increased anticoagulant effects.

Drug interaction studies were performed with azithromycin and other drugs likely to be co-administered.When used in therapeutic doses, azithromycin had a modest effect on the pharmacokinetics of atorvastatin, carbamazepine, cetirizine, didanosine, efavirenz, fluconazole, indinavir, midazolam, rifabutin, sildenafil, theophylline (intravenous and oral), triazolam, trimethoprim/sulfamethoxazole or zidovudine. Co-administration with efavirenz, or fluconazole had a modest effect on the pharmacokinetics of azithromycin. No dosage adjustment of either drug is recommended when azithromycin is coadministered with any of the above agents.

Interactions with the drugs listed below have not been reported in clinical trials with azithromycin; however, no specific drug interaction studies have been performed to evaluate potential drug-drug interaction. Nonetheless, they have been observed with macrolide products. Until further data are developed regarding drug interactions when azithromycin and these drugs are used concomitantly, careful monitoring of patients is advised: Digoxin-elevated digoxin concentrations. Ergotamine or dihydroergotamine-acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia. Terfenadine, cyclosporine, hexobarbital and phenytoin concentrations.

Laboratory Test Interactions

There are no reported laboratory test interactions.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential. Azithromycin has shown no mutagenic potential in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay. No evidence of impaired fertility due to azithromycin was found.

4.6. Pregnancy and lactation

Teratogenic Effects

Pregnancy Category B: Reproduction studies have been performed in rats and mice at doses up to moderately maternally toxic dose concentrations (i.e., 200 mg/kg/day). These doses, based on a mg/m2 basis, are estimated to be 4 and 2 times, respectively, the human daily dose of 500 mg. In the animal studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether azithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when azithromycin is administered to a nursing woman.

4.7. Effects on ability to drive and use machines

Azithromycin may cause dizziness and fatigue. Individual response should be determined before driving or performing tasks requiring alertness.

4.8. Undesirable effects

In clinical trials, most of the reported side effects were mild to moderate in severity and were reversible upon discontinuation of the drug. Potentially serious side effects of angioedema and cholestatic jaundice were reported rarely. Approximately 0.7% of the patients (adults and pediatric patients) from the 5-day multiple-dose clinical trials discontinued azithromycin therapy because of treatment-related side effects. In adults given 500 mg/day for 3 days, the discontinuation rate due to treatment-related side effects was 0.6%. In clinical trials in pediatric patients given 30 mg/kg, either as a single dose or over 3 days, discontinuation from the trials due to treatment-related side effects was approximately 1%. Most of the side effects leading to discontinuation were related to the gastrointestinal tract, e.g., nausea, vomiting, diarrhea, or abdominal pain.

Clinical

Adults

Multiple-dose regimens

Overall, the most common treatment-related side effects in adult patients receiving multiple-dose regimens of azithromycin were related to the gastrointestinal system with diarrhea/loose stools (4 to 5%), nausea (3%) and abdominal pain (2 to 3%) being the most frequently reported.

No other treatment-related side effects occurred in patients on the multiple-dose regimens of azithromycin with a frequency greater than 1%. Side effects that occurred with a frequency of 1% or less included the following:

Cardiovascular: Palpitations, chest pain.

Gastrointestinal: Dyspepsia, flatulence, vomiting, melena and cholestatic jaundice.

Genitourinary: Monilia, vaginitis and nephritis.

Nervous System: Dizziness, headache, vertigo and somnolence.

General: Fatigue.

Allergic: Rash, pruritus, photosensitivity and angioedema.

Single 1-gram dose regimen

Overall, the most common side effects in patients receiving a single-dose regimen of 1 gram of azithromycin were related to the gastrointestinal system and were more frequently reported than in patients receiving the multiple-dose regimen.

Side effects that occurred in patients on the single one-gram dosing regimen of azithromycin with a frequency of 1% or greater included diarrhea/loose stools (7%), nausea (5%), abdominal pain (5%), vomiting (2%), dyspepsia (1%) and vaginitis (1%).

Single 2-gram dose regimen

Overall, the most common side effects in patients receiving a single 2-gram dose of azithromycin were related to the gastrointestinal system. Side effects that occurred in patients in this study with a frequency of 1% or greater included nausea (18%), diarrhea/loose stools (14%), vomiting (7%), abdominal pain (7%), vaginitis (2%), dyspepsia (1%) and dizziness (1%). The majority of these complaints were mild in nature.

4.9. Overdose

No information provided.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Microbiology

Azithromycin demonstrates activity *in vitro* against a wide range of bacteria including the following:

Gram-positive aerobic bacteria - *Staphylococcus aureus, Streptococcus pyogenes* (group A beta-haemolytic streptococci), *Streptococcus pneumoniae*, alpha-haemolytic streptococci (viridans group) and other streptococci, and *Corynebacterium diphtheriae*. Azithromycin demonstrates cross resistance with erythromycin resistant-positive strains, including *Streptococcus faecalis* (enterococcus) and most strains of methicillin-resistant staphylococci.

Gram-negative aerobic bacteria - *Haemophilus influenzae (including beta-lactamase producing Haemophilus influenzae), Haemophilus parainfluenzae, Moraxella catarrhalis,*

Acinetobacter species, Yersinia species, Legionella pneumophila, Bordetella pertussis, Bordetella parapertussis, Shigella species, Pasteurella species, Vibrio cholerae and parahaemolyticus, Plesiomonas shigelloides. Activities against Escherichia coli, Salmonella enteritidis, Salmonella typhi, Enterobacter species, Aeromonas hydrophila and Klebsiella species are variable and susceptibility tests should be performed.

Proteus species, *Serratia* species, *Morganella* species and *Pseudomonas aeruginosa* are usually resistant.

Anaerobic bacteria - *Bacteroides fragilis* and *Bacteroides*species, *Clostridium perfringens*, *Peptococcus* species, *Peptostreptococcus* species, *Fusobacterium necrophorum* and *Propionibacterium acnes*.

Organisms of sexually transmitted diseases - azithromycin is active against *Chlamydia trachomatis* and also shows good activity against *Treponema pallidum*, *Neisseria gonorrhoeae* and *Haemophilus ducreyi*.

Other organisms - *Borrelia burgdorferi* (Lyme disease agent), *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, *Mycoplasma hominis*, *Ureaplasma urealyticum*, *Campylobacter* species and *Listeria monocytogenes*.

Opportunistic pathogens associated with human immunodeficiency virus (HIV) infections - *Mycobacterium avium-intracellulare complex*.

Azithromycin demonstrates activity *in vivo* against the following bacteria:

Gram-positive aerobic bacteria - *Staphylococcus aureus*, *Streptococcus pyogenes* (group A beta-haemolytic streptococci), *Streptococcus pneumoniae*, alpha-haemolytic streptococci (viridans group) and other streptococci.

Gram-negative aerobic bacteria - *Haemophilus influenzae* (including beta-lactamase producing *Haemophilus influenzae), Haemophilus parainfluenzae*, *Moraxella catarrhalis.*

Other organisms - *Chlamydia trachomatis, Chlamydia pneumoniae, Mycoplasma pneumoniae.*

Opportunistic pathogens associated with HIV infections - *Mycobacterium avium-intracellulare complex*.

In Australia, macrolide resistance for *Streptococcus pneumoniae* and *Staphylococcus aureus* has been increasing since the late 1990's. Resistance rates of 15% or more are regularly reported. The use of macrolides should be guided by culture susceptibility results and practice guidelines.

Susceptibility testing

Dilution or diffusion techniques, either quantitative (minimal inhibitory concentration, MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (e.g. National Committee for Clinical Laboratory Standards). Standardised susceptibility test

procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures.

A report of "Susceptible" indicates that the pathogen is likely to be inhibited when the patient is given the recommended dose. A report of "Intermediate" indicates that the result should be considered equivocal, and if the micro-organism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body site where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small uncontrolled technical factors from causing major discrepancies in interpretation.

A report of "Resistant" indicates that the pathogen is not likely to be inhibited when the patient is given the recommended dose. Other therapy should be selected.

Note: The prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections.

Susceptibility testing for *Mycobacterium avium* complex (MAC)

The disk diffusion techniques and dilution methods for susceptibility testing against Gram-positive and Gram-negative bacteria should not be used for determining azithromycin MIC values against mycobacteria. *In-vitro* susceptibility testing methods and diagnostic products currently available for determining MIC values against MAC organisms have not been established or validated. Azithromycin MIC values will vary depending on the susceptibility testing method employed, composition and pH of media and the utilization of nutritional supplements. Breakpoints used to determine whether clinical isolates of *M. avium* or *M. intracellulare* are susceptible to azithromycin but have not been established.

5.2. Pharmacokinetic properties

Absorption

Following oral administration of a single 500 mg dose to fasted subjects, mean maximum serum concentration (C_{max}) of 0.24 to 0.87 µg/mL was achieved in about 1.0 to 3.5 hours, with a mean area under the curve (AUC_{0-24}) of 3.05 µg.hr/mL. The absolute bioavailability of azithromycin is 37%.

The extent of absorption is unaffected by co-administration with antacid. However, C_{max} is reduced by up to 30%. Administration of cimetidine (800 mg) 2 hours prior to azithromycin had no effect on the absorption of azithromycin.

Azithromycin did not affect the plasma levels or pharmacokinetics of carbamazepine, methylprednisolone, zidovudine or multiple oral doses of theophylline (see **Interactions**).

Distribution

Azithromycin is distributed widely throughout the body. Rapid movement of azithromycin from blood into tissues results in significantly higher azithromycin concentrations in tissue than in plasma (from 1 to 60 times the maximum observed concentration in plasma). It appears to be concentrated intracellularly. Concentrations in tissues, e.g. lung, tonsil and prostate, exceed the MIC_{90} for likely pathogens after a single dose of 500 mg, and remain high after serum or plasma concentrations decline to below detectable levels. Mean peak concentrations observed in peripheral leucocytes, the site of MAC infection, were 140 μg/mL and remained above 32 μg/mL for approximately 60 hours following a single 1,200 mg oral dose.

The serum protein binding of azithromycin is variable in the concentration range approximating human exposure, decreasing from 51% at 0.02 μg/mL to 7% at 2 μg/mL.

Metabolism

In vitro and *in vivo* studies to assess the metabolism of azithromycin have not been performed.

Elimination

Serum concentrations decline in a polyphasic pattern, resulting in an average terminal half-life of 68 hours. The high values for apparent steady-state volume of distribution (31.1 L/kg) and plasma clearance (630 mL/min) suggest that the prolonged half-life is due to extensive uptake and subsequent release of drug from tissues. Azithromycin concentrations in the cerebrospinal fluid are very low. Concentrations in the peritoneal fluid are also very low.

Approximately 12% of an intravenously administered dose is excreted in the urine over three days as the parent drug, the majority in the first 24 hours. Biliary excretion of azithromycin is a major route of elimination for unchanged drug following oral administration. Very high concentrations of unchanged drug have been found, together with ten metabolites, formed by N- and O-demethylation, by hydroxylation of the desosamine and aglycone rings, and by cleavage of the cladinose conjugate. Comparison of HPLC and microbiological assays in tissues suggests that metabolites play no part in the microbiological activity of azithromycin.

Special patient groups

Pharmacokinetics in elderly subjects is substantially the same and no dosage adjustment is necessary.

Following a single oral dose of azithromycin 1 g, the pharmacokinetics in subjects with mild to moderate renal impairment (GFR 10 to 80 mL/min) was not affected. Statistically significant differences in AUC_{0-120} (8.8 μg.hr/mL versus 11.7 μg.hr/mL), C_{max} (1.0 μg/mL versus 1.6 μg/mL) and Cl_{Cr} (2.3 mL/min/kg versus 0.2 mL/min/kg) were observed between subjects with severe renal impairment (GFR < 10 mL/min) and subjects with normal renal function.

In patients with mild (Class A) to moderate (Class B) hepatic impairment, there is no evidence of a marked change in serum pharmacokinetics of azithromycin compared to those with normal hepatic function. In these patients, urinary recovery of azithromycin appears to increase, perhaps, to compensate for reduced hepatic clearance.

Azithromycin did not affect the prothrombin time response to a single dose of warfarin. However, prudent medical practice dictates a careful monitoring of prothrombin time in all patients.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose Monohydrate

Sodium Starch Glycollate

Microcrystalline Cellulose

Povidone

Isopropyl Alcohol

Magnesium Stearate

Purified Talc

Cross Carmillose Sodium

Methylene Chloride

Ready Mix colour - Instacoat Universal Pink(code no.IC-U-5518)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4. Special precautions for storage

Store in dry place, protected from light, at a temperature 30^0C.

6.5. Nature and contents of container

10 tablets to be packed in a blister made up of printed aluminium foil / clear, rigid, non-toxic PVC film. Such 10 blisters to be packed in a carton with one leaflet.

6.6. Instructions for use/handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

DUPEN LABORATORIES PVT. LTD.
C 1 – 49/36, DEGAM ROAD,
INDUSTRIAL TOWNSHIP
VAPI – 396195
GUJARAT INDIA.