xxxxxxxx-5343

LEVETIRACETAM

IVETRA 250 / IVETRA 500 / IVETRA 1000

250 mg / 500 mg / 1 g Film-Coated Tablet

Anticonvulsant

FORMULATION:

Each film-coated tablet contains:

Levetiracetam ..... 250 mg, 500 mg and 1 g

PRODUCT DESCRIPTION:

Levetiracetam (Ivetra 250) 250 mg is a blue colored, oval shaped, film coated tablet debossed with breakline separating '250' and 'MG' on one side and '1014' on other side.

Levetiracetam (Ivetra 500) 500 mg is a yellow colored, oval shaped, film coated tablet debossed with breakline separating '500' and 'MG' on one side and '1015' on other side.

Levetiracetam (Ivetra 1000) 1 g is a white to off white, oval shaped, film coated tablet debossed with breakline separating '1000' and 'MG' on one side and '1017' on other side.

CLINICAL PHARMACOLOGY:

The mechanism of action of levetiracetam still remains to be fully elucidated but appears to be different from the mechanisms of current antiepileptic medicinal products. In vitro and in vivo experiments suggest that levetiracetam does not alter basic cell characteristics and normal neurotransmission.

In vitro studies show that levetiracetam affects intra neuronal Ca2+ levels by partial inhibition of N-type Ca2+ currents and by reducing the release of Ca2+ from intraneuronal stores. In addition it partially reverses the reductions in GABA- and glycine-gated currents induced by zinc and β-carbolines. Furthermore, levetiracetam has been shown in in-vitro studies to bind to a specific site in rodent brain tissue. This binding site is the synaptic vesicle protein 2A, believed to be involved in vesicle fusion and neurotransmitter exocytosis. Levetiracetam and related analogs show a rank order of affinity for binding to the synaptic vesicle protein 2A which correlates with the potency of their anti-seizure protection in the mouse audiogenic model of epilepsy. This finding suggests that the interaction between levetiracetam and the synaptic vesicle protein 2A seems to contribute to the antiepileptic mechanism of action of the medicinal product.

Levetiracetam induces seizure protection in a broad range of animal models of partial and primary generalized seizures without having proconvulsant effect. The primary metabolite is inactive.

In man, activity in both partial and generalized epilepsy conditions (epileptiform discharge / photoparoxysmal response) has confirmed the broad spectrum of the preclinical pharmacological profile.

Pharmacokinetic properties

Levetiracetam is readily absorbed from gastrointestinal tract with a bioavailability of almost 100%; peak plasma concentrations are usually achieved within 1.3 hours of oral doses and steady state achieved after 2 days. Plasma protein binding is minimal at less than 10%. Levetiracetam is not extensively metabolized; about 25% of a dose is metabolized by hydroxylation to inactive metabolites. Around 95% of a dose is excreted as unchanged drug and metabolites in the urine. The plasma elimination half-life has been reported to be about 7 hours in adults and children aged 12 years and over; the half-life may be shorter in younger children. Levetiracetam is distributed into breast milk.

Elderly: In elderly patients, the half-life is increased by 40% (ten to eleven hours) and is attributed to the decrease in renal function in this population.

Renal Impairment: The apparent body clearance of both levetiracetam and its major metabolite is correlated to the creatinine clearance. It is therefore recommended to adjust the maintenance daily doe of levetiracetam, based on creatinine clearance in patients with moderate and severe renal impairment. In anuric end stage renal disease subjects: The half-life was approximately 25 and 3.1 hours during interdialytic and intradialytic periods respectively. The fractional removal of levetiracetam was 51% during typical four hour dialysis session.

Hepatic Impairment: In subjects with mild to moderate hepatic impairment, there was no relevant modification of the clearance of levetiracetam. In most subjects with severe hepatic impairment, the clearance of levetiracetam was reduced by more than 50% due to concomitant renal impairment. In patients with severe hepatic impairment, the creatinine clearance may underestimate the renal insufficiency. Therefore 50% reduction of the daily maintenance dose is recommended when creatinine clearance is <70 mL / min.

INDICATIONS:

Used as monotherapy in the treatment of partial onset seizures with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy.

Levetiracetam is indicated as adjunctive therapy :

* in the treatment of partial onset seizures with or without secondary generalization in adults and children from 1 month of age with epilepsy.
* in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic epilepsy.
* in the treatment of primary generalized tonic-clonic seizures in adults and children from 12 years of age with idiopathic Generalized Epilepsy.

DOSAGE AND ADMINISTRATION:

Posology

Monotherapy for Adults and Adolescents from 16 years of Age

The recommended starting dose is 250 mg twice daily which should be increased to an initial therapeutic dose of 500 mg twice daily after two weeks. The dose can be further increased by 250 mg twice daily every two weeks depending upon the clinical response. The maximum dose is 1500 mg twice daily.

Add-on therapy for adults (> 18 years) and adolescents (12 to 17 years) weighing 50 kg or more

The initial therapeutic dose is 500 mg twice daily. The dose can be started on the first day of treatment.

Depending upon the clinical response and tolerability, the daily dose can be increased up to 1,500 mg twice daily. Dose changes can be made in 500 mg twice daily increases or decreases every two to four weeks.

Duration of Treatment

There is no experience with administration of intravenous levetiracetam for longer period than 4 days.

Special Populations

Elderly (65 years and older)

Adjustment of the dose is recommended in elderly patients with compromised renal function.

Renal impairment

The daily dose must be individualized according to renal function.

For adult patients, refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CLcr) in ml/min is needed. The CLcr in ml/min may be estimated from serum creatinine (mg/dl) determination, for adults and adolescents weighing 50 kg or more, the following formula:

$$\text{CLcr (ml/min)} = \frac{[140\text{-age (years)}] \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dl)}} \text{ (x 0.85 for women)}$$

Then CLcr is adjusted for body surface area (BSA) as follows:

$$\text{CLcr (ml/min/1.73 m}^2\text{)} = \frac{\text{CLcr (ml/min)}}{\text{BSA subject (m}^2\text{)}} \times 1.73$$

Dosing adjustment for adult and adolescent patients weighing more than 50 kg with impaired renal function

Group	Creatinine clearance (ml/min/1.73m^2)	Dosage and frequency
Normal	> 80	500 to 1,500 mg twice daily
Mild	50-79	500 to 1,000 mg twice daily
Moderate	30-49	250 to 750 mg twice daily
Severe	< 30	250 to 500 mg twice daily
End-stage renal disease patients undergoing dialysis (1)	-	500 to 1,000 mg once daily (2)

(1) A 750 mg loading dose is recommended on the first day of treatment with levetiracetam.

(2) Following dialysis, a 250 to 500 mg supplemental dose is recommended.

For children with renal impairment, levetiracetam dose needs to be adjusted based on the renal function as levetiracetam clearance is related to renal function. This recommendation is based on a study in adult renally impaired patients.

The CLcr in ml/min/1.73 m^2 may be estimated from serum creatinine (mg/dl) determination using, for young adolescents and children using the following formula (Schwartz formula):

Group	Creatinine clearance (ml/min/1.73 m^2)	Dose and frequency	
		Infants 1 to less than 6 months	Infants 6 to 23 months, children and adolescents weighing less than 50 kg
Normal	> 80	7 to 21 mg/kg (0.07 to 0.21 ml/kg) twice daily	10 to 30 mg/kg (0.10 to 0.30 ml/kg) twice daily
Mild	50-79	7 to 14 mg/kg (0.07 to 0.14 ml/kg) twice daily	10 to 20 mg/kg (0.10 to 0.20 ml/kg) twice daily
Moderate	30-49	3.5 to 10.5 mg/kg (0.035 to 0.105 ml/kg) twice daily	5 to 15 mg/kg (0.05 to 0.15 ml/kg) twice daily
Severe	< 30	3.5 to 7 mg/kg (0.035 to 0.07 ml/kg) twice daily	5 to 10 mg/kg (0.05 to 0.10 ml/kg) twice daily
End-stage renal disease patients undergoing dialysis	--	7 to 14 mg/kg (0.07 to 0.14 ml/kg) once daily (1) (3)	10 to 20 mg/kg (0.10 to 0.20 ml/kg) once daily (2) (4)

(1) A 10.5 mg/kg (0.105 ml/kg) loading dose is recommended on the first day of treatment with levetiracetam.

(2) A 15 mg/kg (0.15 ml/kg) loading dose is recommended on the first day of treatment with levetiracetam.

(3) Following dialysis, a 3.5 to 7 mg/kg (0.035 to 0.07 ml/kg) supplemental dose is recommended.

(4) Following dialysis, a 5 to 10 mg/kg (0.05 to 0.10 ml/kg) supplemental dose is recommended.

Hepatic Impairment

No dose adjustment is needed in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the creatinine clearance may underestimate the renal insufficiency. Therefore 50% reduction of the daily maintenance dose is recommended when creatinine clearance is <60 mL or as prescribed by the physician.

Pediatric Population

The physician should prescribe the most appropriate pharmaceutical form, presentation and strength according to age, weight and dose.

The safety and efficacy of Levetiracetam concentrate for solution for infusion in infants and children less than 4 years have not been established.

Monotherapy

The safety and efficacy of Levetiracetam in children and adolescents below 16 years as monotherapy treatment have not been established.

Children aged 4 to 11 years and adolescents (12 to 17 years) of less than 50 kg

The initial therapeutic dose is 10 mg / kg twice daily.

Depending on the clinical response and tolerability, the dose can be increased up to 30 mg/kg twice daily. Dose changes should not exceed increases or decreases of 10 mg/kg twice daily every two weeks. The lowest effective dose should be used.

Dosage in children 50 kg or greater is the same as in adults.

Dose recommendations for infants from 6 months of age, children and adolescents:

Weight	Starting dose: 10 mg/kg twice daily	Maximum dose: 30 mg/kg twice daily
6 kg (1)	60 mg (0.6 ml) twice daily	180 mg (1.8 ml) twice daily
10 kg (1)	100 mg (1 ml) twice daily	300 mg (3 ml) twice daily
15 kg (1)	150 mg (1.5 ml) twice daily	450 mg (4.5 ml)twice daily
20 kg (1)	200 mg (2 ml) twice daily	600 mg (6 ml) twice daily
25 kg(1)	250 mg twice daily	750 mg twice daily
From 50 kg(2)	500 mg twice daily	1,500 mg twice daily

(1) Children 25 kg or less should preferably start the treatment with Levetiracetam 100mg/ml oral solution.

(2) Dosage in children and adolescents 50 kg or more is the same as in adults.

Add-on therapy for infants from 1 month to less than 6 months:

The tablet formulation is not adapted for use in infants under the age of 6 months. The oral solution is the formulation to use in infants.

The initial therapeutic dose is 7 mg/kg twice daily.

Depending upon the clinical response and tolerability, the dose can be increased up to 21 mg/kg twice daily. Dose changes should not exceed increases or decreases of 7 mg/kg twice daily every two weeks. The lowest effective dose should be used.

Infants should start the treatment with Levetiracetam 100 mg/ml oral solution.

Dose recommendations for infants less than 6 months:

Weight	Starting dose: 7 mg/kg twice daily	Maximum dose: 21 mg/kg twice daily
4 kg	28 mg (0.3 ml) twice daily	84 mg (0.85 ml) twice daily
5 kg	35 mg (0.35 ml) twice daily	105 mg (1.05 ml) twice daily
7 kg	49 mg (0.5 ml)twice daily	147 mg (1.5 ml) twice daily

Three presentations are available:

– A 300 ml bottle with graduated oral syringe containing up to 1000 mg levetiracetam (corresponding to 10 ml) with a graduation every 0.25 ml (corresponding to 25 mg).

This presentation should be prescribed for children older than 4 years, adolescents and adults.

– A 150 ml bottle with graduated oral syringe containing up to 300 mg levetiracetam (corresponding to 3 ml) with a graduation every 0.1 ml (corresponding to10 mg)

In order to ensure the accuracy of the dosing, the smaller bottle (150 ml) and syringe graduated from 0.1 to 3 ml per graduation of 0.1 ml should be prescribed for infants older than 6 months and young children.

– A 150 ml bottle with graduated oral syringe containing up to 100 mg levetiracetam (corresponding to 1 ml) with a graduation every 0.05 ml (corresponding to 5 mg)

In order to ensure the accuracy of the dosing, the smaller bottle (150 ml) and syringe graduated from 0.05 to 1 ml per graduation of 0.05 ml should be prescribed for infants less than 6 months.

Method of administration - tablets

The film-coated tablets must be taken orally, swallowed with a sufficient quantity of liquid and may be taken with or without food. The daily dose is administered in two equally divided doses.

CONTRAINDICATIONS:

Hypersensitivity to levetiracetam or other pyrrolidone derivatives or any of the excipients.

WARNING AND PRECAUTIONS:

In accordance with current clinical practice, if Levetiracetam has to be discontinued it is recommended to withdraw it gradually (e.g. in adults and adolescents weighing more than 50 kg: 500 mg decreases twice daily every two to four weeks; children and adolescents weighing less than 50 kg: dose decrease should not exceed 10 mg/kg twice daily every two weeks.)

The administration of Levetiracetam to patients with renal impairment may require dose adjustment. In patients with severely impaired hepatic function, assessment of renal function is recommended before dose selection.

Suicide, suicide attempt, suicidal ideation and behavior have been reported in patients treated with anti-epileptic agents (including levetiracetam). A meta-analysis of randomized placebo-controlled trials of anti-epileptic drugs has shown a small increased risk of suicidal thoughts and behavior. The mechanism of this risk is not known.

Therefore patients should be monitored for signs of depression and/or suicidal ideation and behaviors and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of depression and/or suicidal ideation or behavior emerge.

Paediatric population

Available data in children did not suggest impact on growth and puberty. However, long term effects on learning, intelligence, growth, endocrine function, puberty and childbearing potential in children remain unknown.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Due to possible different individual sensitivity, some patients might experience somnolence or other central nervous system related symptoms, especially at the beginning of treatment or following a dose increase. Therefore, caution is recommended in those patients when performing skilled tasks, e.g. driving vehicles or operating machinery. Patients are advised not to drive or use machines until it is established that their ability to perform such activities is not affected.

ADVERSE EFFECTS:

Summary of the safety profile

The adverse event profile presented below is based on the analysis of pooled placebo-controlled clinical trials with all indications studied, with a total of 3,416 patients treated with levetiracetam. These data are supplemented with the use of levetiracetam in corresponding open-label extension studies, as well as post-marketing experience. The most frequently reported adverse reactions were nasopharyngitis, somnolence, headache, fatigue and dizziness. The safety profile of levetiracetam is generally similar across age groups (adult and paediatric patients) and across the approved epilepsy indications.

Tabulated list of adverse reactions

Adverse reactions reported in clinical studies (adults, adolescents children and infants > 1 month) and from post-marketing experience are listed in the following table per System Organ Class and per frequency. very common (1/10); common (1/100 to <1/10); uncommon (1/1,000 to <1/100); rare (1/10,000 to <1/1,000) and very rare (<1/10,000),

- Infections and infestations

Very Common: nasopharyngitis

Rare : infection

- Blood and lymphatic system disorders

UnCommon: thrombocytopenia, leukopenia (1)

Rare -neutropenia (1), pancytopenia (1,2)

- Metabolism and nutrition disorders

Common: anorexia,

Uncommon: weight decreased (1), weight increase

- Psychiatric disorders

Common: depression, anxiety(1), insomnia, nervousness/irritability,

Uncommon: abnormal behaviour(1), anger(1), anxiety, confusional state(1), affect lability/mood swings, agitation, hallucination(1), psychotic disorder(1), suicide attempt(1), suicidal ideation(1) .

Rare: Completed suicide(1), personality disorder, thinking abnormal

- Nervous system disorders

Very common: somnolence,

Common: Convulsion, balance disorder, dizziness, lethargy, tremor

UnCommon: amnesia, coordination abnormal/ataxia, disturbance in attention, memory impairment, paraesthesia(1)

Rare, choreoathetosis(1), dyskinesia(1), hyperkinesia

- Eye disorders

UnCommon: diplopia, vision blurred

- Ear and labyrinth disorders

Common: vertigo

- Respiratory, thoracic and mediastinal disorders

Common: cough

- Gastrointestinal disorders

Common: abdominal pain, diarrhea, dyspepsia, nausea, vomiting.

Rare: pancreatitis(1)

- Hepatobiliary disorders

Uncommon:, liver function test abnormal(1)

Rare: hepatic failure(1), hepatitis(1)

- Skin and subcutaneous tissue disorders

Common: rash,

Uncommon: Alopecia(1), eczema, pruritus

Rare: toxic epidermal necrolysis(1), Stevens-Johnson syndrome(1), erythema multiforme(1)

- Musculoskeletal and connective tissue disorders

UnCommon: Muscular weakness, myalgia

- General disorders and administration site conditions

common: asthenia/fatigue.

- Injury, poisoning and procedural complications

UnCommon: injury

(1) Adverse reactions added during post marketing experience.

(2) Bone marrow suppression identified in some of the cases.

Description of selected adverse reactions

The risk of anorexia is higher when topiramate is coadministered with levetiracetam.

In several cases of alopecia, recovery was observed when levetiracetam was discontinued.

Pediatric population

In patients aged 1 month to less than 4 years, a total of 190 patients have been treated with levetiracetam in placebo-controlled and open label extension studies. Sixty (60) of these patients were treated with levetiracetam in placebo-controlled studies. In patients aged 4-16 years, a total of 645 patients have been treated with levetiracetam in placebo-controlled and open label extension studies. 233 of these patients were treated with levetiracetam in placebo-controlled studies. In both these paediatric age ranges, these data are supplemented with the post-marketing experience of the use of levetiracetam.

The adverse event profile of levetiracetam is generally similar across age groups and across the approved epilepsy indications. Safety results in paediatric patients in placebo-controlled clinical studies were consistent with the safety profile of levetiracetam in adults except for behavioural and psychiatric adverse reactions which were more common in children than in adults. In children and adolescents aged 4 to 16 years, vomiting (very common, 11.2%), agitation (common, 3.4%), mood swings (common, 2.1%), affect lability (common, 1.7%), aggression (common, 8.2%), abnormal behaviour (common, 5.6%), and lethargy (common, 3.9%) were reported more frequently than in other age ranges or in the overall safety profile. In infants and children aged 1 month to less than 4 years, irritability (very common, 11.7%) and coordination abnormal (common, 3.3%) were reported more frequently than in other age groups or in the overall safety profile.

A double-blind, placebo-controlled pediatric safety study with a non-inferiority design has assessed the cognitive and neuropsychological effects of Levetiracetam in children 4 to 16 years of age with partial onset seizures. It was concluded that Levetiracetam was not different (non inferior) from placebo with regard to the change from baseline of the Leiter-R Attention and Memory, Memory Screen Composite score in the per-protocol population. Results related to behavioral and emotional functioning indicated a worsening in Levetiracetam treated patients on aggressive behavior as measured in a standardized and systematic way using a validated instrument (CBCL Achenbach Child Behavior Checklist). However subjects, who took Levetiracetam in the long-term open label follow-up study, did not experience a worsening, on average, in their behavioral and emotional functioning; in particular measures of aggressive behaviour were not worse than baseline.

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph or to TORRENT: www.torrentpharma.com".

Patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear.

Overdose

Symptoms

Somnolence, agitation, aggression, depressed level of consciousness; respiratory depression and coma were observed with Levetiracetam overdoses.

Management of overdose

After an acute overdose, the stomach may be emptied by gastric lavage or by induction of emesis. There is no specific antidote for levetiracetam. Treatment of an overdose will be symptomatic and may include haemodialysis. The dialyser extraction efficiency is 60 % for levetiracetam and 74 % for the primary metabolite.

DRUG INTERACTIONS:

Reports from clinical studies in adults indicate that Levetiracetam did not influence the serum concentrations of existing antiepileptic medicinal products (phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin and primidone) and that these antiepileptic medicinal products did not influence the pharmacokinetics of Levetiracetam.

As in adults, there is no evidence of clinically significant medicinal product interactions in pediatric patients receiving up to 60 mg/kg/day levetiracetam.

A retrospective assessment of pharmacokinetic interactions in children and adolescents with epilepsy (4 to 17 years) confirmed that adjunctive therapy with orally administered levetiracetam did not influence the steady-state serum concentrations of concomitantly administered carbamazepine and valproate. However, data suggested a 20% higher levetiracetam clearance in children taking enzyme-inducing antiepileptic medicinal products.

Dosage adjustment is not required.

Probenecid (500 mg four times daily), a renal tubular secretion blocking agent, has been shown to inhibit the renal clearance of the primary metabolite but not of levetiracetam. Nevertheless, the concentration of this metabolite remains low. It is expected that other medicinal products excreted by active tubular secretion could also reduce the renal clearance of the metabolite. The effect of levetiracetam on probenecid was not studied and the effect of levetiracetam on other actively secreted medicinal products, e.g. NSAIDs, sulfonamides and methotrexate, is unknown.

Levetiracetam 1,000 mg daily did not influence the pharmacokinetics of oral contraceptives (ethinyl-estradiol and levonorgestrel); endocrine parameters (luteinizing hormone and progesterone) were not modified. Levetiracetam 2,000 mg daily did not influence the pharmacokinetics of digoxin and warfarin; prothrombin times were not modified. Co-administration with digoxin, oral contraceptives and warfarin did not influence the pharmacokinetics of levetiracetam.

No data on the influence of antacids on the absorption of levetiracetam are available.

The extent of absorption of levetiracetam was not altered by food, but the rate of absorption was slightly reduced.

No data on the interaction of levetiracetam with alcohol are available.

PREGNANCY AND LACTATION:

There are no adequate data from the use of Levetiracetam in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for human is unknown.

Levetiracetam should not be used during pregnancy and in women of childbearing potential not using contraception unless clearly necessary.

As with other antiepileptic medicinal products, physiological changes during pregnancy may affect levetiracetam concentration. Decrease in levetiracetam plasma concentrations has been observed during pregnancy. This decrease is more pronounced during the third trimester (up to 60% of baseline concentration before pregnancy). Appropriate clinical management of pregnant women treated with levetiracetam should be ensured. Discontinuation of antiepileptic treatments may result in exacerbation of the disease which could be harmful to the mother and the fetus.

Levetiracetam is excreted in human breast milk. Therefore, breast-feeding is not recommended.

STORAGE:

Store at temperatures not exceeding 30^{o}C.

CAUTION:

Food, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY :

Levetiracetam (Ivetra 250) 250 mg Film-Coated Tablet - ALU/PVC/PVDC Blister Pack of 10's (Box of 60's) - DRP-2408

DATE OF FIRST AUTHORIZATION:

January 22, 2010

Levetiracetam (Ivetra 500) 500 mg Film-Coated Tablet - ALU/PVC/PVDC Blister Pack of 10's (Box of 60's) - DRP-2409

DATE OF FIRST AUTHORIZATION:

October 15, 2009

Levetiracetam (Ivetra 1000) 1 g Film-Coated Tablet - ALU/PVC/PVDC Blister Pack of 10's (Box of 60's) - DRP-2410

DATE OF FIRST AUTHORIZATION:

October 14, 2009

DATE OF REVISION:

July 2016

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.

Imported and Distributed by :
TORRENT PHARMA PHILIPPINES INC.
Units 3 & 4, 34th Floor, Zuellig Building
Makati Avenue Corner Paseo de Roxas
Makati City, PHILIPPINES

PRODUCT NAME	: IVETRA	**COUNTRY :** Philippines	**LOCATION :** Indrad		**Supersedes A/W No.:**	
ITEM / PACK	: Insert	**NO. OF COLORS:** 1	**REMARK : Folded Size 35 mm**			
DESIGN STYLE	: Front Back	**PANTONE SHADE NOS.:**	**SUBSTRATE :**			
CODE	: xxxxxxxx-5343	**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM) (LxWxH)	: 150 x 470	Prepared By	**Pkg.Dev**			
ART WORK SIZE	: S/S	Reviewed By	**Pkg.Dev**			
DATE	: 22-07-2016	Approved By	**Quality**			
		Black				

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.