FRESENIUS KABI

ONDANSETRON FRESENIUS 2 mg/mL Injection

i.v./i.m. Injection

COMPOSITION
Each mL Injection contains:
Ondansetron Hydrochloride Dihydrate equal to Ondansetron 2 mg

LIST OF EXCIPIENTS
Citric acid anhydrous
Sodium citrate
Sodium chloride
Water for injections

Product Description
Ondansetron Fresenius 2 mg/mL Injection is a clear, colorless and no odor solution

PHARMACOLOGY
Pharmacotherapeutic group, ATC Code
Serotonin ($5HT_3$) antagonist, A04AA01

Mechanism of action
Ondansetron is a potent, highly selective $5HT_3$ receptor antagonist. Its precise mode of action in the control of nausea and vomiting is not known.
Chemotherapeutic agents and radiotherapy may cause release of 5HT in the small intestine initiating a vomiting reflex by activating vagal afferents via $5HT_3$ receptors. Ondansetron blocks the initiation of this reflex.
Activation of vagal afferents may also cause a release of 5HT in the area postrema, located on the floor of the fourth ventricle, and this may also promote emesis through a central mechanism. Thus, the effect of ondansetron in the management of the nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is probably due to antagonism of $5HT_3$ receptors on neurons located both in the peripheral and central nervous system.
The mechanisms of action in post-operative nausea and vomiting are not known but there may be common pathways with cytotoxic induced nausea and vomiting.

Pharmacodynamics (PD)
Ondansetron does not alter plasma prolactin concentrations.

QT Prolongation
The effect of ondansetron on the QTc interval was evaluated in a double blind, randomised, placebo and positive (moxifloxacin) controlled, crossover study in 58 healthy adult men and women. Ondansetron doses included 8 mg and 32 mg infused intravenously over 15 minutes. At the highest tested dose of 32 mg, the maximum mean (upper limit of 90% CI) difference in QTcF from placebo after baseline-correction was 19.6 (21.5) msec. At the lower tested dose of 8 mg, the maximum mean (upper limit of 90% CI) difference in QTcF from placebo after baseline-correction was 5.8 (7.8) msec. In this study, there were no QTcF measurements greater than 480 msec and no QTcF prolongation was greater than 60 msec. No significant changes were seen in the measured electro- cardiographic PR or QRS intervals.

Pharmacokinetics (PK)
The pharmacokinetic properties of ondansetron are unchanged on repeat dosing.

Absorption
Equivalent systemic exposure is achieved after IM and IV administration of ondansetron.

Distribution
Ondansetron is not highly protein bound (70 to 76%).
The disposition of ondansetron following oral, IM or IV dosing in adults is similar with a steady state volume of distribution of about 140 L.

Metabolism
Ondansetron is cleared from the systemic circulation predominantly by hepatic metabolism through multiple enzymatic pathways. The absence of the enzyme CYP2D6 (the debrisoquine polymorphism) has no effect on ondansetron's pharmacokinetics.

Elimination
Ondansetron is cleared from the systemic circulation predominantly by hepatic metabolism. Less than 5% of the absorbed dose is excreted unchanged in the urine.
The disposition of ondansetron following oral, IM or IV dosing is similar with a terminal elimination half life of about 3 hours.

INDICATION
Adults
Ondansetron Fresenius 2 mg/mL Injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.
Ondansetron Fresenius 2 mg/mL Injection is also indicated for the prevention and treatment of post-operative nausea and vomiting.

Paediatric Population
Ondansetron Fresenius 2 mg/mL Injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy.

CONTRAINDICATION
Based on reports of profound hypotension and loss of consciousness when ondansetron was administered with apomorphine hydrochloride, concomitant use with apomorphine is contraindicated (see section **INTERACTIONS**).
Hypersensitivity to any components of the preparation (see sections **WARNING AND PRECAUTION** and **UNDESIRABLE EFFECTS**).

WARNING AND PRECAUTION
Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective $5HT_3$ receptor antagonists.
Ondansetron prolongs the QT interval in a dose-dependent manner (see section **PHARMACOLOGY**). In addition, post-marketing cases of Torsade de Pointes have been reported in patients using ondansetron. Avoid ondansetron in patients with congenital long QT syndrome. Ondansetron should be administered with caution to patients who have or may develop prolongation of QTc, including patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias or patients taking other medicinal products that lead to QT prolongation or electrolyte abnormalities.
Therefore, caution should be exercised in patients with cardiac rhythm or conduction disturbances, in patients treated with anti-arrhythmic agents or beta-adrenergic blocking agents and in patients with significant electrolyte disturbances.
Myocardial ischemia has been reported in patients treated with ondansetron. In some cases, predominantly during intravenous administration, the symptoms appeared immediately after administration but recovered with prompt treatment. Therefore, caution should be exercised during and after administration of ondansetron.
Hypokalemia and hypomagnesemia should be corrected prior to ondansetron administration.
Serotonin syndrome has been described following the concomitant use of Ondansetron Fresenius 2 mg/mL Injection and other serotonergic drugs (see section **INTERACTIONS**). If concomitant treatment with Ondansetron Fresenius 2 mg/mL Injection and other serotonergic drugs is clinically warranted, appropriate observation of the patient is advised.
As Ondansetron Fresenius 2 mg/mL Injection is known to increase large bowel transit time, patients with signs of subacute intestinal obstruction should be monitored following administration.

UNDESIRABLE EFFECTS
Summary of the safety profile
Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10,000 to <1/1000) and very rare (<1/10,000), including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. The incidence in placebo was taken into account. Rare and very rare events were generally determined from post-marketing spontaneous data.
The following frequencies are estimated at the standard recommended doses of Ondansetron Fresenius 2 mg/mL Injection. The adverse event profiles in children and adolescents were comparable to that seen in adults.

Immune system disorders
Rare : Immediate hypersensitivity reactions sometimes severe, including anaphylaxis.

Nervous system disorders
Very common : Headache.
Uncommon : Seizures, movement disorders (including extrapyramidal reactions such as dystonic reactions, oculogyric crisis and dyskinesia) have been observed without definitive evidence of persistent clinical sequelae.
Rare : Dizziness predominantly during rapid IV administration.

Eye disorders
Rare : Transient visual disturbances (e.g. blurred vision) predominantly during IV administration.
Very rare : Transient blindness predominantly during IV administration.
The majority of the blindness cases reported resolved within 20 minutes. Most patients had received chemotherapeutic agents, which included cisplatin. Some cases of transient blindness were reported as cortical in origin.

Cardiac disorders
Uncommon : Arrhythmias, chest pain with or without ST segment depression, bradycardia.
Rare : QTc prolongation (including Torsade de Pointes)

Vascular disorders
Common : Sensation of warmth or flushing.
Uncommon : Hypotension.

Respiratory, thoracic and mediastinal disorders
Uncommon : Hiccups

Gastrointestinal disorders
Common : Constipation
Local burning sensation following insertion of suppositories

Hepatobiliary disorders
Uncommon : Asymptomatic increases in liver function tests#
#These events were observed commonly in patients receiving chemotherapy with ciplastin.

Skin and subcutaneous tissue disorders
Very rare : Toxic skin eruption, including toxic epidermal necrolysis

General disorders and administration site conditions
Common : Local IV injection site reactions

Adverse drug reactions from spontaneous reports and literature cases (frequency not known)
The following adverse drug reactions have been derived from post-marketing experience with ondansetron via spontaneous case reports and literature cases. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorized as not known. Adverse drug reactions are listed according to system organ classes in MedDRA.

Cardiac disorders
Myocardial ischemia

DOSAGE AND ADMINISTERING PROCEDURE
Dosing Regimen
CHEMOTHERAPY AND RADIOTHERAPY INDUCED NAUSEA AND VOMITING (CINV and RINV)
The emetogenic potential of cancer treatment varies according to the doses and combinations of chemotherapy and radiotherapy regimens used. The selection of dose regimen should be determined by the severity of the emetogenic challenge.

CINV and RINV in Adults
The recommended intravenous (IV) or intramuscular (IM) dose of Ondansetron Fresenius 2 mg/mL Injection is 8 mg administered immediately before treatment.
For highly emetogenic chemotherapy, a maximum initial ondansetron dose of 16 mg IV infused over 15 minutes may be used. A single IV dose greater than 16 mg should not be given due to dose-dependent increase of QT prolongation risk (see sections **WARNING AND PRECAUTION, UNDESIRABLE EFFECTS, PHARMACOLOGY**).
The efficacy of Ondansetron Fresenius 2 mg/mL Injection in highly emetogenic chemotherapy may be enhanced by the addition of a single IV dose of dexamethasone sodium phosphate 20 mg, administered prior to chemotherapy.
IV doses greater than 8 mg and up to a maximum of 16 mg must be diluted in 50 mL to 100 mL of 0.9% Sodium Chloride Injection or 5% Dextrose Injection before administration and infused over not less than 15 minutes. Ondansetron Fresenius 2 mg/mL Injection doses of 8 mg or less, do not need to be diluted and may be administered as a slow IM or IV injection in not less than 30 seconds.
The initial dose of Ondansetron Fresenius 2 mg/mL Injection may be followed by 2 additional IV or IM doses of 8 mg by 2 to 4 hours apart, or by a constant infusion of 1 mg/h for up to 24 hours.

CINV in Children and Adolescents (aged 2 years and over)
In children with a body surface area of 0.6 to 1.2 m^2 ondansetron is administered as a single IV dose of 5 mg/m^2 immediately before chemotherapy, followed by 4 mg orally 12 hours later. 4 mg orally twice daily can be continued for up to five days after a course of treatment.

CINV and RINV in Elderly
In patients 65 to 74 years of age, the initial IV dose of Ondansetron Fresenius 2 mg/mL Injection 8 mg or 16 mg, infused over 15 minutes, may be followed by 2 doses of 8 mg infused over 15 minutes and given no less than 4 hours apart. All IV doses should be diluted in 50-100 mL of saline or other compatible infusion fluid and infused over 15 minutes.
In patients 75 years of age or older, the initial IV dose of Ondansetron Fresenius 2 mg/mL Injection should not exceed 8 mg infused over 15 minutes. The initial dose of 8 mg may be followed by 2 doses of 8 mg, infused over 15 minutes and given no less than 4 hours apart (see section **PHARMACOLOGY**). All IV doses should be diluted in 50-100 mL of saline or other compatible infusion fluid and infused over 15 minutes.

180 mm

260 mm

PACKAGING DEVELOPMENT - DC DIVISION

PT. ETHICA Industri Farmasi
Joint Venture with FRESENIUS KABI

Part Description	Leaflet Ondansetron Inj SG
Part No./Edition No.	PB01-1329 / 2/2032
Material / Finishing	HVS 60 gsm
Dimension	260 x 180 mm
Pharmacode No.	196
Type Folded	(A1-A2) + (B1-B2)
Color	P Black U

Software used for TD	Adobe Illustrator CC	
Font :	Font Type	Size
Brand Name :	-	-
Generic Brand Name :	**Myriad Pro - Bold**	**13 pt**
Composition, etc. :	**Arial**	**6 pt**

For Export Product

Change History

PIC	Version	Date	Time	Revision Change
TDN	00	30/05/2018	-	New
	01	20/06/2018	15.47	Change product name, take out Product Registration Holder Name and Address,
				add full address of PT. Ethica
	02	05/07/2018	10.17	Revise redactional refer to Leaflet KH/MM & change size from “160x180mm” to “80x180mm”
	03	16/07/2018	14.01	Change part description (take out MY)
	04	17/07/2018	10.35	Change generic brand name “ONDANSETRON FRESENIUS 2mg/mL Concentrate for
				Solution for Infusion” to “Ondansetron Hydrochloride Dihydrate 2 mg/mL Injection”
	05	20/07/2018	12.54	Add packsize 100s for Ondansetron 4mg/2mL
	06	04/09/2018	18.00	Change brand name from “ONDANSETRON HYDROCHLORIDE DIHYDRATE
				2 mg/mL Injection” to “Ondansetron Fresenius 2 mg/mL Injection”
DEP	07	03/12/2019	15.00	Queries from authority (25 Nov 2019) - Revise redaction refer to innovator, add
				sections (Interactions, Pregnancy and Lactation, Overdosage), change dimension
				(80x180 mm to 260x180 mm), change type folded ((A1-A2) to (A1-A2) + (B1-B2))
	08	13/02/2020	15.44	Queries from authority (06 Feb 2020) - Add Product Description, Incompatibilities,
				Compatibility with other drugs, Pharmaceutical Particulars, revise Packing
		17/02/2020	14.39	Revision from country (17 Feb 2020) - Move list of excipients position, remove
				“Pharmaceutical Particulars” and word "unpreserved" in Incompatibilities
	09	22/04/2020	11.15	Revision from country (22 Apr 2020) - Add “Risk Summary” and “Human Data”
	10	12/07/2021	15.57	Add reg no., part no. & edition no.
	11	18/03/2022	14.44	Revision as LWG meeting (23 Sep 2021) - revision on Warning and Precaution
				and Undesirable Effects, change part description, change edition no., change
				pharmacode

POST-OPERATIVE NAUSEA AND VOMITING
PONV in Adults
For prevention of post-operative nausea and vomiting, the recommended dose of Ondansetron Fresenius 2 mg/mL Injection is a single dose of 4 mg by IM or slow IV injection administered at the induction of anaesthesia.
For treatment of established post-operative nausea and vomiting a single dose of 4 mg given by IM or slow IV injection is recommended.

PONV in Children and Adolescents (aged 2 years and over)
For prevention and treatment of PONV in paediatric patients having surgery performed under general anaesthesia, Ondansetron Fresenius 2 mg/mL Injection may be administered by slow IV injection (not less than 30 seconds) at a dose of 0.1 mg/kg up to a maximum of 4 mg either prior to, at or after induction of anaesthesia, or after surgery.
There is limited data on the use of Ondansetron Fresenius 2 mg/mL Injection in the prevention and treatment of PONV in children under 2 years of age.

PONV in Elderly
There is limited experience in the use of Ondansetron Fresenius 2 mg/mL Injection in the prevention and treatment of post-operative nausea and vomiting in the elderly, however Ondansetron Fresenius 2 mg/mL Injection is well tolerated in patients over 65 years receiving chemotherapy.

Special populations
Renal Impairment
No alteration of daily dosage or frequency of dosing, or route of administration are required.

Hepatic Impairment
Clearance of ondansetron is significantly reduced and serum half-life significantly prolonged in subjects with moderate or severe impairment of hepatic function. In such patients a total daily dose of 8 mg IV should not be exceeded.

Patients with Poor Sparteine/Debrisoquine Metabolism
The elimination half-life of ondansetron is not altered in subjects classified as poor metabolisers of sparteine and debrisoquine. Consequently in such patients repeat dosing will give drug exposure levels no different from those of the general population. No alteration of daily dosage or frequency of dosing is required.

INTERACTIONS
There is no evidence that Ondansetron Fresenius 2 mg/mL Injection either induces or inhibits the metabolism of other drugs commonly co-administered with it. Specific studies have shown that there are no pharmacokinetic interactions when Ondansetron Fresenius 2 mg/mL Injection is administered with alcohol, temazepam, furosemide, tramadol or propofol.
Ondansetron is metabolised by multiple hepatic cytochrome P-450 enzymes: CYP3A4, CYP2D6 and CYP1A2. Due to the multiplicity of metabolic enzymes capable of metabolising ondansetron, enzyme inhibition or reduced activity of one enzyme (e.g. CYP2D6 genetic deficiency) is normally compensated by other enzymes and should result in little or no significant change in overall ondansetron clearance or dose requirement.
Use of Ondansetron Fresenius 2 mg/mL Injection with QT prolonging drugs and/or drugs that cause electrolyte abnormalities may result in additional QT prolongation. Concomitant use of Ondansetron Fresenius 2 mg/mL Injection with cardiotoxic drugs (e.g. anthracyclines) may increase the risk of arrhythmias. Therefore, caution should be exercised when ondansetron is co-administered with drugs that prolong the QT interval and/or cause electrolyte abnormalities and/or cardiotoxic drugs (see section **WARNING AND PRECAUTION**).

Apomorphine
Based on reports of profound hypotension and loss of consciousness when ondansetron was administered with apomorphine hydrochloride, concomitant use with apomorphine is contraindicated.

Phenytoin, Carbamazepine and Rifampicin
In patients treated with potent inducers of CYP3A4 (i.e. phenytoin, carbamazepine and rifampicin), the oral clearance of ondansetron was increased and ondansetron blood concentrations were decreased.

Serotonergic Drugs (e.g., SSRIs and SNRIs)
Serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) has been described following the concomitant use of Ondansetron Fresenius 2 mg/mL Injection and other serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs) and serotonin noradrenaline reuptake inhibitors (SNRIs) (see section **WARNING AND PRECAUTION**).

Tramadol
Data from small studies indicate that ondansetron may reduce the analgesic effect of tramadol.

PREGNANCY AND LACTATION
Pregnancy
The safety of Ondansetron Fresenius 2 mg/mL Injection for use in human pregnancy has not been established.
Reproductive studies in rats and rabbits did not show evidence of harm to the fetus when ondansetron was administered during organogenesis at approximately 6 and 24 times the maximum recommended human oral dose of 24 mg/day, based on body surface area, respectively. However as animal studies are not always predictive of human response the use of Ondansetron Fresenius 2 mg/mL Injection in pregnancy is not recommended (see **Animal data**).
Safety data of ondansetron in pregnancy are limited, and findings from available pharmaco-epidemiologic studies are inconsistent.
Post-marketing reports describe cases of congenital malformations with use of Ondansetron Fresenius 2 mg/mL Injection during pregnancy; however the reports are insufficient to establish a causal relationship.

Risk Summary
In human epidemiological studies, an increase in orofacial clefts was observed in infants of women administered ondansetron during the first trimester of pregnancy. Regarding cardiac malformations the epidemiological studies showed conflicting results (see **Human data**).
The use of ondansetron in pregnancy is not recommended.

Human Data
Three epidemiological studies in the US assessed the risk of specific congenital anomalies, including orofacial clefts and cardiac malformations in offspring born to mothers exposed to ondansetron during the first trimester of pregnancy.
One cohort study with 88,467 ondansetron exposed pregnancies showed an increased risk of oral clefts (3 additional cases per 10,000 women treated, adjusted relative risk (RR), 1.24 (95% CI 1.03-1.48)) without an apparent increase in risk of cardiac malformations.
One case-control study using population-based birth defect registries with 23,200 cases across two datasets reported an increased risk of cleft palate in one dataset and no increased risk in the other dataset. There was no increased risk of cardiac malformations in this study.
The second case-control study found no statistically significant increase in orofacial cleft or cardiac malformations in 76,330 ondansetron exposed mothers, but found an increased risk of cardiac malformations (adjusted odds ratio (OR) of 1.43 (95% CI 1.28-1.61)) only in a subset (5,557) of patients treated in the medical office or hospital setting.

Animal data
In embryo-fetal development studies in rats and rabbits, pregnant animals received oral doses of ondansetron up to 15 mg/kg/day and 30 mg/kg/day, respectively, during the period of organogenesis. With the exception of a slight decrease in maternal body weight gain in the rabbits, there were no significant effects of ondansetron on the maternal animals or the development of the offspring. At doses of 15 mg/kg/day in rats and 30 mg/kg/day in rabbits, the maternal dose was approximately 6 and 24 times the maximum recommended human oral dose of 24 mg/day, respectively, based on body surface area. In a pre- and postnatal developmental toxicity study, pregnant rats received oral doses of ondansetron up to 15 mg/kg/day from Day 17 of pregnancy to litter Day 21. With the exception of a slight reduction in maternal body weight gain, there were no effects upon the pregnant rats and the pre- and postnatal development of their offspring, including reproductive performance of the mated F1 generation. At a dose of 15 mg/kg/day in rats, the maternal dose was approximately 6 times the maximum recommended human oral dose of 24 mg/day based on BSA.

Lactation
Risk Summary
It is not known whether Ondansetron Fresenius 2 mg/mL Injection is transferred into human milk. There are no data on the effects of Ondansetron Fresenius 2 mg/mL Injection on the breastfed child or the effects of Ondansetron Fresenius 2 mg/mL Injection on milk production. However, it has been demonstrated that ondansetron passes into the milk of lactating animals. It is therefore recommended that mothers receiving Ondansetron Fresenius 2 mg/mL Injection should not breast-feed their babies.

Females and males of reproductive potential
Pregnancy testing
Pregnancy status should be verified for females of reproductive potential prior to starting the treatment with Ondansetron Fresenius 2 mg/mL Injection.

Contraception
Females of reproductive potential should be advised that it is possible that Ondansetron Fresenius 2 mg/mL Injection can cause harm to the developing fetus. Sexually active females of reproductive potential are recommended to use effective contraception (methods that result in less than 1% pregnancy rates) when using Ondansetron Fresenius Injection 2 mg/mL during the treatment and for two days after stopping treatment with Ondansetron Fresenius 2 mg/mL Injection.

Infertility
There is no effect of Ondansetron Fresenius 2 mg/mL Injection on fertility.

OVERDOSAGE
There is limited experience of Ondansetron Fresenius 2 mg/mL Injection overdose. In the majority of cases symptoms were similar to those already reported in patients receiving recommended doses (see section **UNDESIRABLE EFFECTS**). Manifestations that have been reported include visual disturbances, severe constipation, hypotension and a vasovagal episode with transient second degree AV block. In all instances, the events resolved completely.
Ondansetron prolongs QT interval in a dose-dependent fashion. ECG monitoring is recommended in cases of overdose.
Cases consistent with serotonin syndrome have been reported in young children following oral overdose.

Treatment
There is no specific antidote for Ondansetron Fresenius 2 mg/mL Injection, therefore in cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate.
The use of ipecacuanha to treat overdose with Ondansetron Fresenius 2 mg/mL Injection is not recommended as patients are unlikely to respond due to the anti-emetic action of ondansetron itself.

Incompatibilities
Compatibility with IV fluids
Compatibility studies have shown that Ondansetron Fresenius 2 mg/mL Injection is stable for 48 hours at 30 ± 2°C with the following i.v infusion fluids:
- Sodium Chloride IV infusion 0.9% w/v
- Dextrose IV infusion 5% w/v
- Ringers IV infusion

Compatibility with other drugs
Ondansetron may be administered by IV infusion at 1 mg/h, from an infusion bag or syringe pump. The following drugs may be administered via the Y-site of the ondansetron giving set for ondansetron concentrations of 16 to 160 micrograms/mL (e.g. 8 mg/500 mL and 8 mg/50 mL respectively):

Cisplatin	Concentrations up to 0.48 mg/mL (e.g. 240 mg in 500 mL) administered over 1 to 8 hours.
Carboplatin	Concentrations in the range 0.18 mg/mL to 9.9 mg/mL (e.g. 90 mg in 500 mL to 990 mg in 100 mL), administered over 10 minutes to 1 hour.
Etoposide	Concentrations in the range 0.144 mg/mL to 0.25 mg/mL (e.g. 72 mg in 500 mL to 250 mg in 1 L), administered over 30 minutes to one hour.
Ceftazidime	Doses in the range 250 mg to 2000 mg reconstituted with Water for Injections BP as recommended by the manufacturer (e.g. 2.5 mL for 250 mg and 10 mL for 2 g ceftazidime) and given as an IV bolus injection over approximately 5 minutes.
Cyclo-phosphamide	Doses in the range 100 mg to 1 g, reconstituted with Water for Injections BP, 5 mL per 100 mg cyclophosphamide, and given as an IV bolus injection over approximately 5 minutes.
Doxorubicin	Doses in the range 10 to 100 mg reconstituted with Water for Injections BP, 5 mL per 10 mg doxorubicin, as recommended by the manufacturer and given as an IV bolus injection over approximately 5 minutes.

PACKING :
Ondansetron Fresenius 2 mg/mL Injection is filled in type I clear glass ampoule of 2 mL and 5 mL
- Box, 5 ampoules @ 2mL, Reg. No. SIN16020P
- Box, 5 ampoules @ 4 mL, Reg. No. SIN16020P
- Box, 100 ampoules @ 2mL, Reg. No. SIN16020P

Manufactured and Batch Released by:
PT. ETHICA Industri Farmasi
Bekasi - Indonesia
Kawasan Industri Jababeka Tahap V, Blok B1B1,
Desa Jayamukti, Kecamatan Cikarang Pusat,
Kabupaten Bekasi, Jawa Barat - Indonesia

PB01-1329
2/2032

180 mm

260 mm

Artwork Design
☐ Submission
☐ Commercial

PD DC	RA DC	Quality PU	Country RA Approval