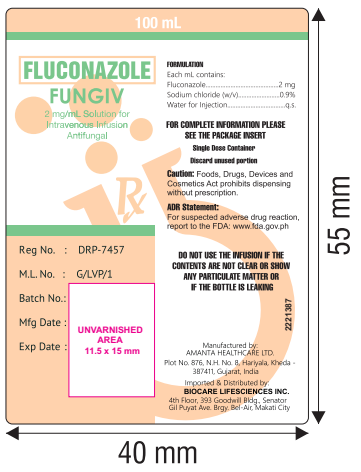
Amanta Healthcare Ltd.
Artwork Format

CUSTOMER NAME	**Amanta Export Biocare Lifesciences Ltd. (Philippines)**				
PRODUCT / GENERIC NAME & PACK SIZE	**Fungiv (Fluconazole Infusion 2mg/ml)**	**Lang. English**	**100 ml**	DT OF PREPARATION	**02/07/2022**
NAME OF PACKING MTS. & SIZE (MM)	**Label size: 40 (L) X 55 (H) mm.**		**(Line-2)**	DT OF REVISION	**-**
COLOUR	**CMYK**			VERSION NO.	**00**
ARTWORK CODE				PREPARED BY	**RAHUL**
ITEM CODE	**2221387**	CHANGE CONTROL NO.:		SUPERSEDES CODE	

Actual size



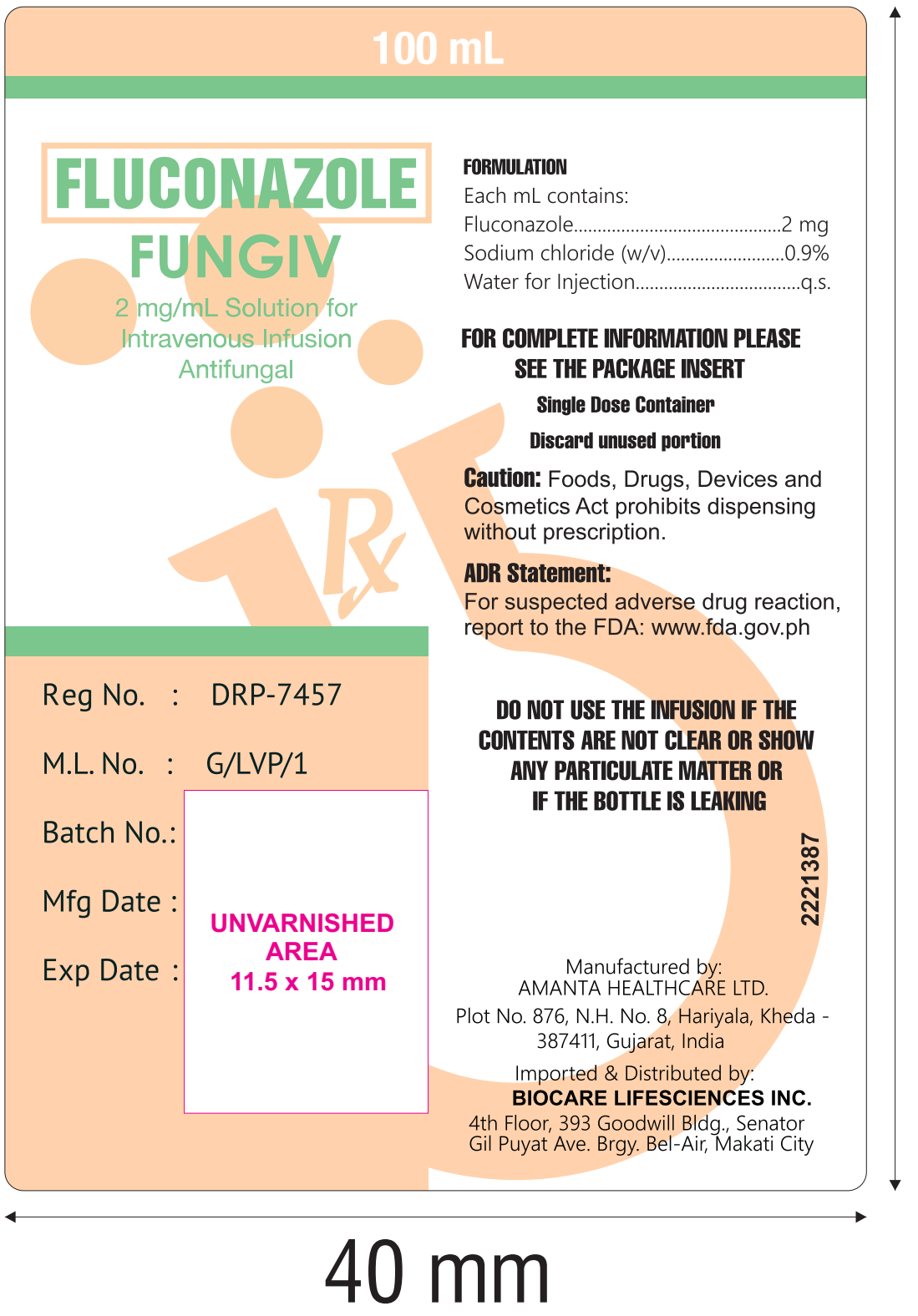
APPROVED

Mary Grace Adora Marzan, RPh
Regulatory Affairs Officer
Biocare Lifesciences, Inc.
20 July 2022

Artwork
THINK CREATIVE

IMPORTANT : IN CASE OF ANY MISMATCH IN FONTS/DESIGN OR COLOR SHADE, PLEASE DO NOT PROCEED WITHOUT CONFIRMATION.
THIS COPY IS ONLY FOR REVIEW AND RECORD PURPOSE "NOT FOR SCALING".

Enlarge size



NOTE:

	DEPT	DESIGNATION	NAME	SIGNATURE	DATE
INITIATED BY	SALES				
CHECKED BY	RA / F & D				
	QC				
APPROVED BY	PRODUCTION				
	QA				
AUTHORIZED BY	QA				

CUSTOMER NAME	**Amanta Export Biocare Lifesciences Ltd. (Philippines)**				
PRODUCT / GENERIC NAME & PACK SIZE	**Fungiv (Fluconazole Infusion 2mg/ml) Lang. English 100 ml**			DT OF PREPARATION	**02/07/2022**
NAME OF PACKING MTS. & SIZE (MM)	**Carton size: 48 (L) X 35 (W) X 153 (H) mm. (Line-2)**			DT OF REVISION	**-**
COLOUR	**CMYK**			VERSION NO.	**00**
ARTWORK CODE				PREPARED BY	**RAHUL**
ITEM CODE	**2230476**	CHANGE CONTROL NO.:		SUPERSEDES CODE	

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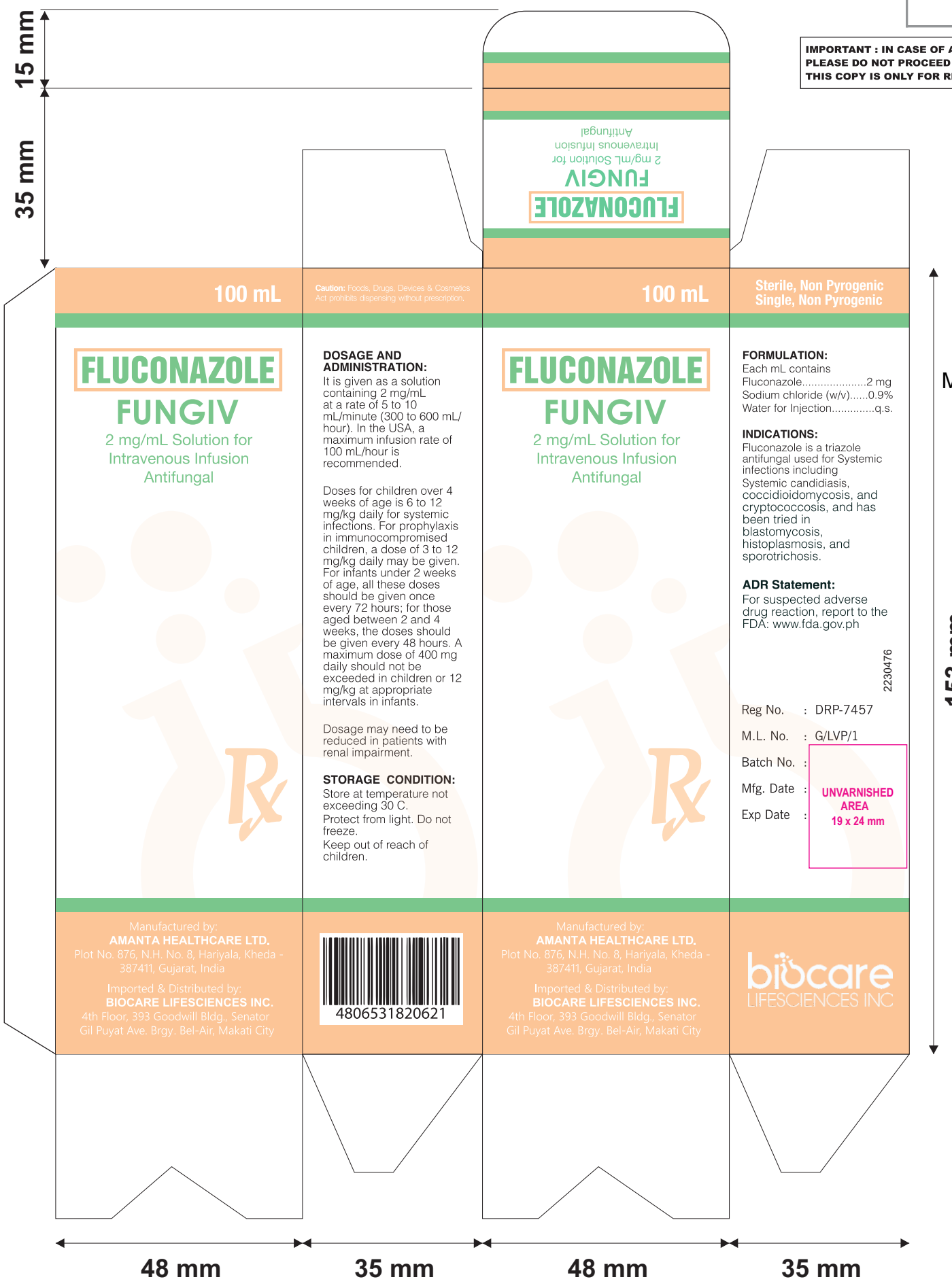
Actual size



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NOTE:

	DEPT	DESIGNATION	NAME	SIGNATURE	DATE
INITIATED BY	SALES				
CHECKED BY	RA / F & D				
	QC				
APPROVED BY	PRODUCTION				
	QA				
AUTHORIZED BY	QA				

Amanta Healthcare Ltd.
Artwork Format

Amanta

CUSTOMER NAME	**Amanta Export Biocare Lifesciences Ltd. (Philippines)**				
PRODUCT / GENERIC NAME & PACK SIZE	**Fungiv (Fluconazole Infusion 2mg/ml)** **Lang. English** **100 ml**			DT OF PREPARATION	**02/07/2022**
NAME OF PACKING MTS. & SIZE (MM)	**Insert size: 95 (L) X 200 (H) mm., *Folding size: 95 x 25 mm.***			DT OF REVISION	**-**
COLOUR	**Black 100% & 60%**			VERSION NO.	**00**
ARTWORK CODE				PREPARED BY	**RAHUL**
ITEM CODE	**2240476**	CHANGE CONTROL NO.:		SUPERSEDES CODE	

Artwork
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Biocare Lifesciences, Inc.
20 July 2022

Actual Size

FLUCONAZOLE

FUNGIV

2 mg/mL Solution for
Intravenous Infusion
Antifungal

FORMULATION:
Each mL contains:
Fluconazole..... 2 mg
Sodium chloride (w/v)..... 0.9%
Water for Injection..... q.s.

INDICATIONS:
Fluconazole is a triazole antifungal used for systemic infections including systemic candidiasis, coccidioidomycosis, and cryptococcosis, and has been tried in blastomycosis, histoplasmosis, and sporotrichosis.

DOSAGE AND ADMINISTRATION:
It is given as a solution containing 2 mg/mLat a rate of 5 to 10 mL/minute (300 to 600 mL/hour). In the USA, a maximum infusion rate of 100 mL/hour is recommended.
Doses for children over 4 weeks of age is 6 to 12 mg/kg daily for systemic infections. For prophylaxis in immunocompromised children, a dose of 3 to 12 mg/kg daily may be given. For infants under 2 weeks of age, all these doses should be given once every 72 hours; for those aged between 2 and 4 weeks, the doses should be given every 48 hours. A maximum dose of 400 mg daily should not be exceeded in children, or 12 mg/kg at appropriate intervals in infants.

Dosage may need to be reduced in patients with renal impairment.

PHARMACOKINETICS:
Fluconazole is well absorbed after oral doses, bioavailability from the oral route being 90% or more of that from the intravenous route. Mean peak plasma concentrations of 6.72 micrograms/mL have been reported in healthy subjects after a 400-mg oral dose. Peak concentrations are reached within 1 to 2 hours of oral doses. Plasma concentrations are proportional to the dose over a range of 50 to 400 mg. Multiple dosing leads to increases in peak plasma concentrations; steady-state concentrations are reached in 5 to 10 days but may be attained on day 2 if a loading dose is given.

Fluconazole is widely distributed and the apparent volume of distribution is close to that of total body water. Concentrations in breast milk, joint fluid, saliva, sputum, vaginal fluids, and peritoneal fluid are similar to those achieved in plasma. Concentrations in the CSF range from 50 to 90% of plasma concentrations, even in the absence of meningeal inflammation. Protein binding is only about 12%. About 80% of a dose is excreted unchanged in the urine and about 11% as metabolites. The elimination half-life of fluconazole is about 30 hours and is increased in patients with renal impairment. Fluconazole is removed by dialysis.

ADVERSE EFFECTS:
Adverse effects reported with fluconazole most commonly affect the gastrointestinal tract and include abdominal pain, diarrhoea, flatulence, nausea and vomiting, and taste disturbance. Other adverse effects include headache, dizziness, leucopenia, thrombocytopenia, hyperlipidaemias, and raised liver enzyme values. Serious hepatotoxicity has been reported in patients with severe underlying disease such as AIDS or malignancy. Anaphylaxis and angioedema have been reported rarely.

Skin reactions are rare but exfoliative cutaneous reactions such as toxic epidermal necrolysis and Stevens- Johnson syndrome have occurred, more commonly in patients with AIDS.

PRECAUTIONS:
Fluconazole should be used with caution in patients with impaired hepatic or renal function. Abnormalities in haematological, hepatic, and renal-function tests have been observed in patients with serious underlying diseases such as AIDS or malignancy. Cases of torsade de pointes and QT prolongation have been reported rarely and caution is advised when giving fluconazole to patients with proarrhythmic conditions. Teratogenicity has occurred in animals given high doses of fluconazole and its use is not recommended in pregnancy.

INTERACTIONS:
In general, fewer interactions are considered to occur with fluconazole than with either itraconazole or ketoconazole. Use of rifampicin with fluconazole results in reduced plasma concentrations of fluconazole. Use of hydrochlorothiazide and fluconazole has resulted in clinically insignificant increases in plasma fluconazole concentrations.

Fluconazole may interfere with the metabolism of some other drugs, mainly through inhibition of the cytochrome P450 isoenzymes CYP3A4 and CYP2C9. This may account for the reported increases in plasma concentrations of bosentan, ciclosporin, midazolam, nevirapine, amitriptyline, nortriptyline, phenytoin, rifabutin, sulfonylurea hypoglycaemics and nateglinide, selective cyclo-oxygenase-2- inhibitors such as celecoxib and parecoxib, tacrolimus, triazolam, warfarin, and zidovudine; fluconazole may inhibit the formation of a toxic metabolite of sulfamethoxazole.

Increases in terfenadine concentrations following high doses of fluconazole have been associated with ECG abnormalities. A similar effect may be anticipated with astemizole. Use of fluconazole with cisapride could result in increased cisapride concentrations and associated toxicity. The use of fluconazole with astemizole, cisapride, or terfenadine should therefore be avoided because of the risk of cardiac arrhythmias. Syncope attributed to increased amitriptyline concentrations has occurred when amitriptyline was given with fluconazole.Fluconazole may also reduce the clearance of theophylline. The concentration of contraceptive steroids has been reported to be both increased and decreased in patients receiving fluconazole and the efficacy of oral contraceptives may be affected.

Antimicrobial Action
Fluconazole is a triazole antifungal drug which in sensitive fungi inhibits cytochrome P450-dependent enzymes, resulting in impairment of ergosterol synthesis in fungal cell membranes. It is active against Blastomyces dermatitidis, Candida spp., Coccidioides immitis, Cryptococcus neoformans, Epidermophyton spp., Histoplasma capsulatum, Microsporum spp., and Trichophyton spp.
Resistance has developed in some Candida spp. following long-term prophylaxis with fluconazole, and cross-resistance with other azoles has been reported.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C. Protect from light. Do not freeze.

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

AVAILABILITY: 100mL LDPE Poly bottle, box of 1s.

ADR STATEMENT: For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Reg No. : DRP-7457

M.L. No. : G/LVP/1

2240476

Amanta
Manufactured by:
AMANTA HEALTHCARE LTD.
Plot No. 876, N.H. No. 8, Hariyala, Kheda - 387411, Gujarat, India

biocare LIFESCIENCES INC
Imported & Distributed by:
BIOCARE LIFESCIENCES INC.
4th Floor, 393 Goodwill Bldg., Senator Gil Puyat Ave. Brgy. Bel-Air, Makati City

200 mm

95 mm

NOTE:

	DEPT	DESIGNATION	NAME	SIGNATURE	DATE
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