Government of Pakistan Ministry of National Health Services, Regulations and Coordination (Drug Regulatory Authority of Pakistan)

Islamabad, the 23rd June, 2023.

NOTIFICATION

S.R.O. 769 (I)/2023. In exercise of the powers conferred by clause (a) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with section 12 of the Drugs Act, 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan with the approval of the Federal Government is pleased to fix maximum retail prices specified in column (4) of the Table below on which the drugs specified in column (2) thereof, having packing sizes specified in column (3) of that table, shall be sold, subject to the condition specified in paragraph 2 of this notification, namely:-

TABLE

	IADLU		
S. No	Drugs / Composition	Pack size	Maximum Retail Price
(1)	(2)	(3)	(4)
1.	Taflotan Ophthalmic Solution 0.0015% w/v Each ml contains; Tafluprost15μg.	1's x 2.5ml	Rs. 1,198 (Originator Brand)
	Imported by: M/s OBS Pakistan (Pvt) Ltd., C-14, Manghopir road, SITE, Karachi. Manufacturer: M/s Santen Pharmaceutical Co., Ltd. Shiga Plant, 348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukamigun, Shiga, Japan.		
	M/s Santen Pharmaceutical Co. Ltd. Shiga Plant will be responsible for: • Preparation of drug solution process • Filtration for sterilization and filling process • Release testing of product and M/s Santen Pharmaceutical Co.,Ltd. Noto Plant, 2-14, Sikinami will be responsible for: • Packaging and labeling process • Release testing of product • Batch release		
	Marketing Authorization Holder: M/s. Santen Pharmaceutical Co., Ltd. Shiga Plant, 348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukami- gun, Shiga, Japan		

S. No	Drugs / Composition	Pack size	Maximum Retail Price
2.	MultiBic 2 mmol/l potassium solution for haemodialysis / haemofiltration. Before Mixing. Each 1000ml solution contains: Acidic electrolyte, glucose solution (small compartment) Active substances: Potassium chloride=2.982 g Calcium chloride dihydrate=4.410 g Magnesium chloride hexahydrate=2.033 g Glucose monohydrate(=anhydrous glucose 20.00 g)=22.00 g K+= 40 mmol Ca2+= 30 mmol Mg2+= 10 mmol Cl-= 122 mmol Glucose = 111 mmol Alkaline hydrogen carbonate solution (large compartment) Active substances: Sodium chloride=6.453 g Sodium hydrogen carbonate=3.104 g Na+= 147 mmol Cl-= 110 mmol HCO3-= 37 mmol AFTER MIXING 1000 ml of the ready-to-use solution contains: Active substances: Sodium chloride = 6.136 g Potassium chloride = 0.1491 g Sodium hydrogen carbonate = 2.940 g Calcium Chloride Dihydrate = 0.2205 g Magnesium Chloride Hexahydrate = 0.1017g Glucose Monohydrate (= anhydrous glucose 1.000 g) = 1.100 g Sodium = 140 mmol Potassium = 2.0 mmol Calcium = 1.5 mmol Magnesium = 0.50 mmol Chloride = 111 mmol Hydrogen Carbonate = 35 mmol Glucose = 5.55 mmol. Manufacturer specifications Haemofiltrates	5000ml (Delivered in a double chamber bag (two-compartment).	Rs.8,541 (Originator Brand)
	Storage conditions after mixing of the two		No.
compartn Chemical	compartments (ready-to-use solution): Chemical and physical in-use stability of the ready-to-use solution has been demonastrated for 48 hours		

S. No	Drugs / Composition	Pack size	Maximum Retail Price
	at 30°C prior to the inlet of the pump unit.		
	From a microbiological point of view, once connected to the haemodialysis, haemofiltration or haemodiafiltration circuit, and as hydrogen carbonate is present, the product shall be used immediately.		
	Imported By:- M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan. Manufacturer.		
	M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany Marketing Authorization Holder. M/s Fresenius Medical Care Deutschland GmbH		
	Else-Kroner- Straße 1 61352 Bad Homburg v.d.H./Germany. MA. No: 50132.00.00 dated 19.02.2002		
3.	MultiBic 4 mmol/l potassium solution for haemodialysis/haemofiltration. BEFORE MIXING Each 1000ml solution contains Acidic electrolyte, glucose solution (small compartment) Active substances: Potassium chloride=5.964 g Calcium chloride dihydrate=4.410 g Magnesium chloride hexahydrate=2.033 g Glucose monohydrate(=anhydrous glucose 20.00 g)=22.00 g K+= 80 mmol Ca2+= 30 mmol Mg2+= 10 mmol Cl-= 162 mmol Glucose=111 mmol Alkaline hydrogen carbonate solution (large compartment) Active substances: Sodium chloride=6.453 g Sodium hydrogen carbonate=3.104 g Na+= 147 mmol Cl-= 110 mmol	5000ml (Delivered in a double chamber bag (two-compartment).	Rs.8541 (Originator Brand)
	HCO3- = 37 mmol AFTER MIXING 1000 ml of the ready-to-use solution contains: Active substances: Sodium chloride=6.136 g Potassium chloride=0.2982 g Sodium hydrogen carbonate=2.940 g		

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	Calcium Chloride Dihydrate = 0.2205 g Magnesium Chloride Hexahydrate = 0.1017 g Glucose Monohydrate (= anhydrous glucose 1.000 g) = 1.100 g Sodium = 140 mmol Potassium = 4.0 mmol Calcium = 1.5 mmol Magnesium = 0.50 mmol Chloride = 113 mmol Hydrogen Carbonate = 35 mmol Glucose = 5.55 mmol Manufacturer specifications Haemofiltrates Storage conditions after mixing of the two compartments (ready-to-use solution): Chemical and physical in-use stability of the ready-to-use solution has been demonastrated for 48 hours		
	at 30°C prior to the inlet of the pump unit. From a microbiological point of view, once connected to the haemodialysis, haemofiltration or haemodiafiltration circuit, and as hydrogen carbonate is present, the product shall be used immediately. Imported By:- M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan. Manufacturer. M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany Marketing Authorization Holder. M/s Fresenius Medical Care Deutschland GmbH Else-Kroner- Straße 1 61352 Bad Homburg		
	v.d.H./Germany. MA. No: 50132.00.00 dated 19.02.2002	50001	Do 9541
4.	MultiBic 3 mmol/l potassium solution for haemodialysis/haemofiltration BEFORE MIXING Each 1000ml solution contains Acidic electrolyte, glucose solution (small compartment) Active substances: Potassium chloride=4.473 g Calcium chloride dihydrate=4.410 g Magnesium chloride hexahydrate=2.033 g Glucose monohydrate(=anhydrous glucose 20.00 g)=22.00 g	5000ml (Delivered in a double chamber bag (two- compartment).	Rs.8541 (Originator Brand)

	V	
	K + = 60 mmol	
1	Ca2+ = 30 mmol	
	Mg2+=10 mmol	
	Cl- = 142 mmol	
- 1	Glucose = 111 mmol	
	Alkaline hydrogen carbonate solution	
- 1	(large compartment)	
- 1	Sodium chloride=6.453 g	
	Sodium hydrogen carbonate=3.104 g	
	Na+ = 147 mmol	
- 1	Cl-= 110 mmol	
- 1	HCO3- = 37 mmol	
	AFTER MIXING	
- 1	1000 ml of the ready-to-use solution contains:	
- 1	Active substances:	
- 1	Sodium chloride=6.136 g	
- 1	Potassium chloride=0.2237 g	
	Sodium hydrogen carbonate=2.940 g	
	Calcium Chloride Dihydrate = 0.2205 g	
	Magnesium Chloride Hexahydrate = 0.1017g	
	Glucose Monohydrate (= anhydrous glucose 1.000	
	g) = 1.100 g Sodium = 140 mmol	
	Potassium = 3.0 mmol	
	Calcium = 1.5 mmol	
	Magnesium = 0.50 mmol Chloride = 112 mmol	
	Hydrogen Carbonate = 35 mmol Glucose = 5.55 mmol	
	Manufacturer specifications	
	Haemofiltrates	
	Storage conditions after mixing of the two compartments (ready-to-use solution):	
	Chemical and physical in-use stability of the ready- to-use solution has been demonastrated for 48 hours at 30°C prior to the inlet of the pump unit.	
	From a microbiological point of view, once connected to the haemodialysis, haemofiltration or haemodiafiltration circuit, and as hydrogen carbonate is present, the product shall be used immediately.	
	Imported By:- M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road	
	Gulberg III, Lahore 54660,Pakistan.	
	Manufacturer.	
	M/s Fresenius Medical Care Deutschland GmbH,	

S. No	Drugs / Composition	Pack size	Maximum Retail Price
	66606 St. Wendel / Germany Marketing Authorization Holder. M/s Fresenius Medical Care Deutschland GmbH Else-Kroner- Straße 1 61352 Bad Homburg v.d.H./Germany. MA. No: 50132.00.00 dated 19.02.2002		
	MultiBic potassium free solution for haemodialysis/haemofiltration BEFORE MIXING Each 1000ml solution contains Acidic electrolyte, glucose solution (small compartment) Active substances: Calcium chloride dihydrate=4.410 g Magnesium chloride hexahydrate=2.033 g Glucose monohydrate(=anhydrous glucose 20.00 g)=22.00 g Ca2+ = 30mmol Mg2+ = 10mmol Cl-= 82mmol Glucose = 111 mmol Alkaline hydrogen carbonate solution (large compartment) Active substances: Sodium chloride=6.453 g Sodium hydrogen carbonate=3.104 g Na+= 147 mmol Cl-= 110 mmol HCO3-= 37 mmol AFTER MIXING 1000 ml of the ready-to-use solution contains: Active substances: Sodium chloride=6.136 g Sodium hydrogen carbonate=2.940 g Calcium Chloride Dihydrate = 0.2205 g Magnesium Chloride Hexahydrate = 0.1017g Glucose Monohydrate (= anhydrous glucose 1.000 g) = 1.100 g Sodium = 1.5 mmol Magnesium = 0.50 mmol Chloride = 109 mmol Hydrogen Carbonate = 35 mmol Glucose = 5.55 mmol Manufacturer specifications Haemofiltrates Storage conditions after mixing of the two compartments (ready-to-use solution):	5000ml (Delivered in a double chamber bag (two-compartment).	Rs.8541 (Originator Brand)

S. No	Drugs / Composition	Pack size	Maximum Retail Pric
	Chemical and physical in-use stability of the ready-to-use solution has been demonastrated for 48 hours at 30°C. it is not recommended to store the ready-to-use solution longer than 48h including duration of treamtment or at a temperature higher than 30°C prior to the inlet of the pump unit.		
	Imported By:- M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan. Manufacturer.		
	M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany Marketing Authorization Holder. M/s Fresenius Medical Care Deutschland GmbH Else-Kroner- Straße 1 61352 Bad Homburg v.d.H./Germany. MA. No: 50132.00.00 dated 19.02.2002		
	Cancidas 70 mg Powder for Injection Caspofungin Acetate (70 mg/vial of Caspofungin free base).	1's	Rs. 37,862 (Originator Brand)
	Imported by: M/s OBS Pakistan (Pvt) Ltd., C-14, Manghopir road, SITE, Karachi. Product License Holder: M/s Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands Manufacturer: M/s Fareva Mirabel, Route de Marsat, Riom, 63963 Clermont-Ferrand, Cedex 9, France (site also responsible for batch release in the EU, quality control, primary and secondary packaging).		
	Cancidas 50 mg Powder for Injection Caspofungin Acetate (50 mg/vial of Caspofungin free base).	l's	Rs. 33,402 (Originator Brand)
	Imported by: M/s OBS Pakistan (Pvt) Ltd., C-14, Manghopir road, SITE, Karachi. Product License Holder: M/s Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands Manufacturer:		
	M/s Fareva Mirabel, Route de Marsat, Riom, 63963 Clermont-Ferrand, Cedex 9, France (site	(

S. No	Drugs / Composition	Pack size	Maximum Retail Price
	also responsible for batch release in the EU, quality control, primary and secondary packaging).		
3.	Rybelsus 3mg tablet Each tablet contains: Semaglutide*3mg *human glucagon-like peptide-1 (GLP-1) analogue produced in Saccharomyces cerevisiae cells by recombinant DNA technology.	10's 30's	Rs.6,800 Rs.19,584 (Originator Brand)
	Imported by: M/s Novo Nordisk Pharma (Private) limited, Karachi.		
	Manufacturer: M/s Novo Nordisk A/S, Novo Nordisk Park, 2760 Malov, Denmark. (also responsible for primary and Secondary packaging). Batch Release: M/s. Novo Nordisk A/S, Novo Alle, 2880 Bagsvaerd, Denmark.		
).	Rybelsus 7mg tablet Each tablet contains: Semaglutide*7mg *human glucagon-like peptide-1 (GLP-1) analogue produced in Saccharomyces cerevisiae cells by recombinant DNA technology.	10's 30's	Rs.7,500 Rs.21,600 (Originator Brand)
	Imported by: M/s Novo Nordisk Pharma (Private) limited,		
	Karachi. Manufacturer: M/s Novo Nordisk A/S, Novo Nordisk Park, 2760 Malov, Denmark. (also responsible for primary and Secondary packaging). Batch Release: M/s. Novo Nordisk A/S, Novo Alle, 2880 Bagsvaerd, Denmark.		
0.	Rybelsus 14mg tablet Each tablet contains: Semaglutide*14mg *human glucagon-like peptide-1 (GLP-1) analogue produced in Saccharomyces cerevisiae cells by recombinant DNA technology.	10's 30's	Rs.8,200 Rs.23,616 (Originator Brand)
	Imported by:	11	

S. No	Drugs / Composition	Pack size	Maximum Retail Price
	M/s Novo Nordisk Pharma (Prvt) Ltd, Karachi. Manufacturer: M/s Novo Nordisk A/S, Novo Nordisk Park, 2760 Malov, Denmark. (also responsible for primary and Secondary packaging). Batch Release: M/s. Novo Nordisk A/S, Novo Alle, 2880 Bagsvaerd, Denmark.		
11.	Visanne (Dienogest) 2mg Tablets Each tablet contains:- Dienogest2mg Imported by: - M/s Bayer Pakistan (Pvt) Ltd., Karachi. Product License Holder: M/s Jenapharm GmbH & Co. KG, Otto-Schott- Strasse 15 D-07745 Jena Germany. Bulk Manufacturer, Packaging and final release:	30's	Rs.7,430 (Originator Brand)
2.	M/s Bayer Weimar GmbH & Co. KG DObereinerstrasse 2099427 Weimar, Germany. Prucalopride Tablet 2mg Each film coated Tablet contains:	10's	Rs.595
13.	Prucalopride (as succinate)	10's	Rs.369
14.		30gm 15gm 60gm	Rs.437 Rs.218 Rs.857
5.	Brivaracetam 50mg/5ml Injection Each 5ml contains: - Brivaracetam 50mg	5mlx1's 5mlx10	Rs.277 Rs.2,659
6.	Brivaracetam 10mg/1ml Oral Solution Each 1ml contains: - Brivaracetam 10mg	120ml 60ml	Rs.2,552 Rs.1,276
17.	Minoxidil 2.5mg Tablet Each uncoated tablet contains: Minoxidil2.5mg	30's 1's	Rs.2,900 Rs.96.66
18.	Azilsartan 80mg Tablets Each tablet Contains: Azilsartan medoxomil (as potassium)80mg	3x10's	Rs.1,495
	Azilsartan 40mg Tablets	30's	Rs.816

Rs.489 Rs.32,767 Rs.64,233 Rs.21,791
Rs.32,767 Rs.64,233
Rs.64,233
Rs.21,791
Rs.5,218 Rs.1044
Rs.17,012 Rs.1701
Rs.3,550
Rs.46,945
1's Rs.1133 3's Rs.3127 5's Rs.5212
1's Rs.1133 3's Rs.3127 5's Rs.5212
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S. No	Drugs / Composition	Pack size	Maximum Retail Price
29.	Sodium Chloride 0.45% IV Infusion Each 100ml Contains: Sodium Chloride450mg	500ml	Rs.60 (without euro cap)
30.	Sodium Chloride + Dextrose Infusion Each 100ml Contains: Sodium Chloride0.18gm Dextrose4.3gm	500ml 500ml	Rs.90 (without Eurocap) Rs.106 (with Eurocap)
3.1.	Esmolol Hydrochloride Injection 10mg/ml IV Each ml contains: Esmolol Hydrochloride	10ml x 5's 10ml x 1's 10ml x10's	Rs.350 Rs.70 Rs.672
32.	Dextromethoprhan Hydrobromide Liquid/Cough Syrup (Suger Free) Each 5ml contains: Dextromethoprhan Hydrobromide7.5mg	120ml	Rs.60
33.	Aspirin 81mg + Omperazole 40mg Tablets Each film coated delayed release tablet contains: Aspirin	10's	Rs.282
34.	Japanese Encephalitis Vaccine Live attenuated (Sterile powder for Injection) Single dose vial Each 0.5ml of reconstituted vaccine contain: not less than 5.4log PFU of Live JE virus	1 vial + 1 ampoule of WFI 10 vials + 10 ampoules of WFI	Rs.2072 Rs.19,891
35.	Japanese Encephalitis Vaccine Japanese Encephalitis Inactivated Vaccine (Human) (Purified Inactivated Vaccine – Adsorbed). Each 0.5mL of Vaccine contains: Purified Inactivated Japanese encephalitis Virus Strain (SA 14-14-2)6 µg Aluminum as Aluminum Hydroxide0.1% w/v Phosphate Buffer Salineq.s.	1 + 1 diluent	Rs.2072
36.	Japanese Encephalitis Vaccine Japanese Encephalitis Inactivated Vaccine (Human) (Purified Inactivated Vaccine – Adsorbed) Single Pediatric dose vial-0.5ml. Each 0.5mL contains: Purified Inactivated Japanese Encephalitis Virus vaccine Strain (SA 14-14-2)3 mcg Aluminum as Aluminum Hydroxide0.1% w/v Phosphate Buffer Salineq.s.	1+ 1 diluent	Rs.1243

S. No	Drugs / Composition	Pack size	Maximum Retail Price
37.	Emgality TM 100mg/ml Solution. Each pre-filled syringe contains: Galcanezumab100mg/ml Imported by: • M/s Elli Lilly Pakistan (Pvt) Ltd, Karachi. Name of Manufacturer: • M/s Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN46285, USA.	3's 1's	Rs.243,327 Rs.81,109 (Originator Brand)
38.	Buprenorphine as HCl 4mg Tablet Each sublingual tablet contains Buprenorphine as HCl4mg	28's 10x10's	Rs.3,128 Rs.10,944
39.	Buprenorphine as HCl 8mg Tablet Each sublingual tablet contains Buprenorphine as HCl8mg	28's 10x10's	Rs.5213 Rs.18,240
40.	Infliximab Solution for Injection Each pre-filled syringe (1mL) contains: Infliximab120mg	vial	Rs.65,313
41.	Iron Sucrose 200mg/10ml Injection Each 10ml contains: Iron Sucrose (Iron (III)-Hydroxide Sucrose Complex) eq. to Elemental Iron	10ml x1's	Rs.872
42.	Carbidopa Anhydrous eq 25mg+Levodopa 100mg Tablet Each sustained release tablet Contains: - Carbidopa Anhydrous Eq25mg Levodopa100mg	30's 100's	Rs.275 Rs.918
43.	Carbidopa Anhydrous eq 50mg + Levodopa 200mg Tablet Each sustained release tablet Contains: - Carbidopa Anhydrous Eq50mg Levodopa200mg	30's 100's	Rs.458 Rs.1530
44.	Diclofenac Sodium Void Gel 1% Each 50gm contains: Diclofenac Sodium 500mg (in the form of Diclofenac Epolamine646.4mg)	20gm 50gm	Rs.96 Rs.227
45.	Thymalfasin 1.6mg /Vial for Injection Each vial contains: Thymalfasin 1.6mg	2's	Rs.26,087
46.	Deferasirox 360mg film coated Tablet Each film coated tablet contains: Deferasirox360mg	30's	Rs.9,029
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S. No	Drugs / Composition	Pack size	Maximum Retail Price
47.	Deferasirox 180mg film coated Tablet Each film coated tablet contains: Deferasirox180mg	30's	Rs.5,418
48.	Epoetin alfa Lyophilized Powder for Injection 2000IU Each vial contains: Epoetin alfa2000IU Diluent: Each Ampoule contains: Water for Injectionlml	1's 12's	Rs.1,694 Rs.19,514
49.	Epoetin alfa Lyophilized Powder for Injection 4000IU Each vial contains: Epoetin alfa	1's 12's	Rs.3,128 Rs.36,034

2. The maximum retail price (MRP) shall be subject to the following condition namely:-

(a) maximum retail price as mentioned in column (4) of the Table shall not be applicable on drug whose registrations under sub-rule (4) of rule 29 of the Dugs (Licensing, Registration and Advertising) Rules, 1976 were issued before the issuance of this notification, unless otherwise stated expressively.

[No.F.11-10/2022-DD (P)]

(Hafiz Bilal Bin Akbar)
Deputy Director (Legal Affairs)

The Manager, Printing Corporation of Pakistan Press, <u>Islamabad</u>