



DESCRIPTION OF PRODUCT GROUP AND TREE

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1) DESCRIPTION OF THE DEVICE

Hemodialysis solution is a solution used in the treatment of acute and chronic renal insufficiency during the hemodialysis process. The hemodialysis solution is used in combination with the hemodialysis machine to remove blood waste.

Hemodialysis solution (dialysate) is an aqueous solution without organic components (with the exception of acetate and glucose added to correct acidity in the blood) with an electrochemical composition similar to that of normal human extracellular fluid. Dialysis is prepared by mixing purified water with concentrated electrolytes and other dissolved substances, depending on the physiological needs of the patient.

The dialysis solution, or dialysate, assists the hemodialysis machine in controlling a safe rate of fluid removal from the body by restoring some of the necessary water and mineral substances, such as sodium (salt) and potassium, during the treatment process. The solution can be adjusted to accommodate the patient and their body's specific blood composition.(7)

Insprasol Haemodialysis Acid and Basic Concentrate, Inspracart Haemodialysis Sodium Bicarbonate Cartridge and Insprabag Haemodialysis Sodium Bicarbonate Bag are produced for treatment of chronic renal failure patients. Our products are major component of system which is designed by ultra purified dialysis water system component to prevent inflammation due to treatment. The electrolyte concentrations in solution is restore plasma levels to clinically desired concentrations or maintain plasma levels at the desired concentration.

Product description can be see table below.

PRODUCT DESCRIPTION	INSPASOL ACID SOLUTION
Device Presentation	HDPE Canister
pH	2.0-3.0
Sterile/ Nonsterile	Non-sterile
Appearance	Clear
Physical State	Liquid
Odor	Vinegar



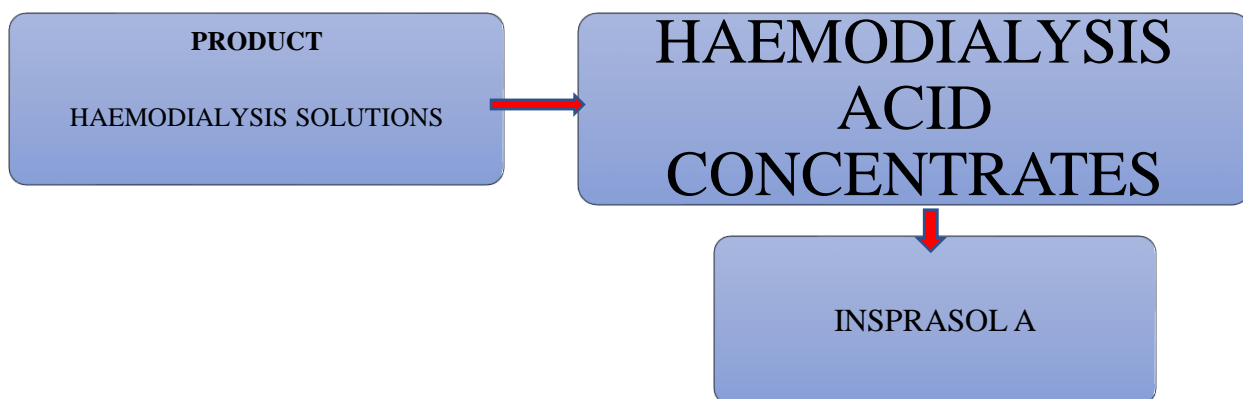
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Radioactivity	N/A
How the Device Achieves Its Intended Purpose	Insprasol solution is used a replacement solution to replace water and electrolytes removed during dialysis. After taking a Bicarbonate in solution is used as an alkalizing buffer to normalize acid-base balance.
Principles of Operation	Use a component only in combination with haemodialysis basic concentrate Using programme and dilution rate with bicarbonate and water is regulated by haemodialysis machine specification and patients treatment requirements.
Materials Used in the Product	Sodium Chloride Potassium Chloride Calcium Chloride Magnesium Chloride Acetic Acid Glucose Monohydrate
Incorporation with a Medicinal Substance	N/A

2. INSPRASOL HAEMODIALYSIS ACID CONCENTRATE PRODUCT TREE





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3. PRODUCT GROUP NAMES, PRODUCT CODES

3.1 INSPRASOL HAEMODIALYSIS ACID CONCENTRATES

NO	PRODUCT CODE	FORMULATION	PACKAGING AMOUNTS
1	INSPRASOL A 1XXX	SPECIFIC	3,78 Liters
2	INSPRASOL A 1XXX	SPECIFIC	5 Liters
3	INSPRASOL A 1XXX	SPECIFIC	7,8 Liters
3	INSPRASOL A 1XXX	SPECIFIC	8 Liters
4	INSPRASOL A 1XXX	SPECIFIC	10 Liters
5	INSPRASOL A 1XXX	SPECIFIC	1000 Liters

4. DESCRIPTION OF INSPRASOL SUBSTANCES:

Each INSPRASOL Haemodialysis Acid Concentrate is included different chemicals according to formulations. The properties of the chemicals used are explained following texts.

1. SODIUM CHLORIDE

1.1. Terminology & Structure

Substance	CAS NO.	Molecular formula	Molar mass
Sodium Chloride	7647-14-5	NaCl	54.44 g mol ⁻¹

1.2. General Properties

Substance	Properties
Sodium Chloride	<ul style="list-style-type: none">- Molar mass: 54.44 g mol⁻¹- Appearance: Colorless Crystals- Physical states: Solid- Odor: Odorless- Density: 2.165 g/cm³- Melting Point: 801°C- Solubility; water, ammonia, methanol

2. POTASSIUM CHLORIDE

2.1. Terminology & Structure

Substance	CAS NO.	Molecular formula	Molar mass
Potassium Chloride	7447-40-7	KCl	74.5513 g mol ⁻¹



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2.2. General Properties

Substance	Properties
Potassium Chloride	<ul style="list-style-type: none">- Molar mass: 74.5513 g mol⁻¹- Appearance: White crystalline solid- Physical states: Solid- Odor: Odorless- Density: 1.984 g/cm³- Melting Point: 770°C- Solubility; water, glycerol, alkalizes- Acidity: ≈7

3. MAGNESIUM CHLORIDE

3.1. Terminology & Structure

Substance	CAS NO.	Molecular formula	Molar mass
Magnesium Chloride (Hexahydrate)	7791-18-6	MgCl ₂	203.31 g mol ⁻¹

3.2. General Properties

Substance	Properties
Magnesium Chloride	<ul style="list-style-type: none">- Molar mass: 203.31 g mol⁻¹- Appearance: White crystalline solid- Physical states: Solid- Odor: Odorless- Density: 2.32 g/cm³- Melting Point: 117°C- Solubility; acetone, ethanol

4. CALCIUM CHLORIDE

4.1. Terminology & Structure

Substance	CAS NO.	Molecular formula	Molar mass
Calcium Chloride (Hexahydrate)	7774-34-7	CaCl ₂	110.98 g mol ⁻¹

4.2. General Properties

Substance	Properties
Calcium Chloride (Hexahydrate)	<ul style="list-style-type: none">- Molar mass: 110.98 g mol⁻¹- Appearance: White crystalline solid- Physical states: Solid- Odor: Odorless- Density: 1.71 g/cm³- Melting Point: 30 °C- Solubility; in water, alcohol- Acidity: 6.5-8.0

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5. ACETIC ACID

5.1. Terminology & Structure

Substance	CAS NO.	Molecular formula	Molar mass
Acetic Acid	64-19-7	CH ₃ COOH	60.05 g mol ⁻¹

5.2. General Properties

Substance	Properties
Acetic Acid	<ul style="list-style-type: none">- Molar mass: 60.05 g mol⁻¹- Appearance: Colorless Liquid- Physical states: Liquid- Odor: Pungent- Density: 1.049 g/cm³- Melting Point: 16.5 °C- Solubility; miscible in water- Acidity: 7.46

6. DEXTROSE

6.1. Terminology & Structure

Substance	CAS NO.	Molecular formula	Molar mass
Dextrose	50-99-7	C ₆ H ₁₂ O ₆	180.16 g mol ⁻¹

6.2. General Properties

Substance	Properties
Dextrose	<ul style="list-style-type: none">- Molar mass: 180.16 g mol⁻¹- Appearance: White Powder- Physical states: Solid- Density: 1.54 g/cm³- Melting Point: 150 °C- Solubility; in water

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7. Formulation List

DILUTION RATE	PRODUCT CODE	Sodium (Na ⁺)	Potassium (K ⁺)	Calcium (Ca ⁺²)	Magnesium (Mg ⁺²)	Chloride (Cl ⁻)	Acetate (CH ₃ COO ⁻)	Bicarbonate HCO ₃ ⁻	Glucose (C ₆ H ₁₂ O ₆)
		mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L	mmol/L
1+34	INSPRASOL A 1001	140	2	1,5	0,5	111	3	32	5,55
1+34	INSPRASOL A 1002	138	2	1	0,5	108	3	32	5,55
1+34	INSPRASOL A 1003	138	1	1,25	0,5	107,5	3	32	5,55
1+34	INSPRASOL A 1004	140	2	1,5	0,5	111	3	32	0
1+34	INSPRASOL A 1005	138	2	1,75	0,5	109,5	3	32	0
1+34	INSPRASOL A 1006	138	2	1,75	0,5	109,5	3	32	5,55
1+34	INSPRASOL A 1007	138	2	1,25	0,5	108,5	3	32	5,55
1+34	INSPRASOL A 1008	138	2	1,5	0,5	109	3	32	5,55
1+34	INSPRASOL A 1009	138	3	1,5	0,5	110	3	32	5,55
1+34	INSPRASOL A 1010	138	3	1	0,5	109	3	32	11,1
1+34	INSPRASOL A 1011	138	1	1	0,5	107	3	32	5,55



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1+34	INSPRASOL A 1012	138	1	1	0,5	107	3	32	11,1
1+34	INSPRASOL A 1013	140	2	1,25	0,5	110,5	3	32	5,55
1+34	INSPRASOL A 1014	138	1	1,5	1	109	3	32	11,1
1+34	INSPRASOL A 1015	140	2	1,25	0,5	110,5	3	32	0
1+34	INSPRASOL A 1016	138	2	1	0,5	108	3	32	0
1+34	INSPRASOL A 1017	138	2	1	0,5	108	3	32	11,1
1+34	INSPRASOL A 1018	140	2	1,75	0,5	111,5	3	32	5,55
1+34	INSPRASOL A 1019	138	1,5	1,75	0,5	109	3	32	5,55
1+34	INSPRASOL A 1020	138	0	1,5	0,5	107	3	32	0
1+34	INSPRASOL A 1021	138	0	1,5	0,5	107	3	32	5,55
1+34	INSPRASOL A 1022	138	1	1	0,5	107	3	32	0
1+34	INSPRASOL A 1023	138	1	1,25	0,5	107,5	3	32	0
1+34	INSPRASOL A 1024	138	2	0,44	0,5	106,88	3	32	5,55
1+34	INSPRASOL A 1025	138	1	1,25	1	108,5	3	32	0
1+34	INSPRASOL A 1026	138	1	1,25	1	108,5	3	32	5,55
1+34	INSPRASOL A 1027	138	2	1,25	0,5	108,5	3	32	0
1+34	INSPRASOL A 1028	138	2	1,25	0,5	108,5	3	32	11,1



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1+34	INSPRASOL A 1029	138	3	1,25	0,5	109,5	3	32	0
1+34	INSPRASOL A 1030	138	3	1,25	0,5	109,5	3	32	5,55
1+34	INSPRASOL A 1031	138	3	1,25	0,5	109,5	3	32	11,1
1+34	INSPRASOL A 1032	138	1	1,5	0,5	108	3	32	0
1+34	INSPRASOL A 1033	138	1	1,5	0,5	108	3	32	5,55
1+34	INSPRASOL A 1034	138	1	1,5	0,5	108	3	32	11,1
1+34	INSPRASOL A 1035	138	2	1,5	0,5	109	3	32	0
1+34	INSPRASOL A 1036	138	2	1,5	0,5	109	3	32	11,1
1+34	INSPRASOL A 1037	138	3	1,5	0,5	110	3	32	0
1+34	INSPRASOL A 1038	138	3	1,5	0,5	110	3	32	11,1
1+34	INSPRASOL A 1039	138	1	1,75	0,5	108,5	3	32	0
1+34	INSPRASOL A 1040	138	1	1,75	0,5	108,5	3	32	5,55
1+34	INSPRASOL A 1041	138	1	1,75	0,5	108,5	3	32	11,1
1+34	INSPRASOL A 1042	140	2	1,75	0,5	111,5	3	32	0
1+34	INSPRASOL A 1043	138	3	1,75	0,5	110,5	3	32	0
1+34	INSPRASOL A 1044	138	3	2	0,5	111	3	32	11,1
1+34	INSPRASOL A 1045	138	0	1,75	0,5	110,5	3	32	5,55



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1+34	INSPRASOL A 1046	140	2	1,5	0,5	111	2	33	5,55
1+34	INSPRASOL A 1047	138	1,5	1,5	0,5	108,5	3	32	5,55
1+34	INSPRASOL A 1048	140	2	1,5	0,5	111	4	31	5,55
1+34	INSPRASOL A 1049	140	2	1,5	0,5	111	4	31	8,33
1+34	INSPRASOL A 1050	140	2	1,5	0,75	111,5	3	32	5,55
1+34	INSPRASOL A 1051	138	2	1,75	0,5	109,5	3	32	5,55
1+34	INSPRASOL A 1052	140	3	1,5	0,5	112	3	32	5,55
1+34	INSPRASOL A 1053	140	1	1	0,5	109	3	32	11,1
1+34	INSPRASOL A 1054	140	1	1,25	0,5	109,5	2	33	0
1+34	INSPRASOL A 1055	138	2	1,75	0,5	106,5	6	32	0
1+34	INSPRASOL A 1056	140	1	1,25	0,5	109,5	2	33	11,1
1+34	INSPRASOL A 1057	140	1	1,25	0,5	109,5	3	32	0
1+34	INSPRASOL A 1058	140	1	1,25	0,5	109,5	3	32	5,55
1+34	INSPRASOL A 1059	140	1	1,25	0,5	109,5	3	32	11,1
1+34	INSPRASOL A 1060	140	1	1,25	0,75	110	3	32	0
1+34	INSPRASOL A 1061	140	1	1,25	0,75	110	3	32	5,55
1+34	INSPRASOL A 1062	140	1,5	1,25	0,5	110	3	32	0



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1+34	INSPRASOL A 1063	140	1,5	1,25	0,5	110	3	32	5,55
1+34	INSPRASOL A 1064	140	1	1,5	0,5	110	2	33	0
1+34	INSPRASOL A 1065	140	1	1,5	0,5	110	2	33	5,55
1+34	INSPRASOL A 1066	140	1	1,5	0,5	110	2	33	11,1
1+34	INSPRASOL A 1067	140	1	1,5	0,5	110	3	32	0
1+34	INSPRASOL A 1068	140	1	1,5	0,5	110	3	32	5,55
1+34	INSPRASOL A 1069	140	1	1,5	0,5	110	3	32	11,1
1+34	INSPRASOL A 1070	140	1	1,5	0,75	110,5	3	32	0
1+34	INSPRASOL A 1071	140	1	1,5	0,75	110,5	3	32	5,55
1+34	INSPRASOL A 1072	140	1	1,5	0,75	110,5	3	32	0
1+34	INSPRASOL A 1073	140	1	1,75	0,5	110,5	2	33	0
1+34	INSPRASOL A 1074	140	1	1,75	0,5	110,5	2	33	5,55
1+34	INSPRASOL A 1075	140	1	1,75	0,5	110,5	2	33	11,1
1+34	INSPRASOL A 1076	140	1,5	1,25	0,5	110	2	33	0
1+34	INSPRASOL A 1077	140	1,5	1,25	0,5	110	2	33	5,55
1+34	INSPRASOL A 1078	140	1,5	1,5	0,5	110,5	2	33	0
1+34	INSPRASOL A 1079	140	1,5	1,5	0,5	110,5	2	33	5,55



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1+34	INSPRASOL A 1080	140	1,5	1,75	0,5	111	2	33	0
1+34	INSPRASOL A 1081	140	1,5	1,75	0,5	111	2	33	5,55
1+34	INSPRASOL A 1082	140	1,5	1,5	0,5	110,5	3	32	0
1+34	INSPRASOL A 1083	140	1,5	1,5	0,5	110,5	3	32	5,55
1+34	INSPRASOL A 1084	140	1,5	1,5	0,5	110,5	3	32	11,1
1+34	INSPRASOL A 1085	140	1	1,75	0,5	110,5	3	32	0
1+34	INSPRASOL A 1086	140	1	1,75	0,5	110,5	3	32	5,55
1+34	INSPRASOL A 1087	140	1	1,75	0,5	110,5	3	32	11,1
1+34	INSPRASOL A 1088	140	1,5	1,75	0,5	111	3	32	0
1+34	INSPRASOL A 1089	140	1,5	1,75	0,5	111	3	32	5,55
1+34	INSPRASOL A 1090	140	1,5	1,75	0,5	111	3	32	11,1
1+34	INSPRASOL A 1091	140	2	1	0,5	110	3	32	0
1+34	INSPRASOL A 1092	140	2	1	0,5	110	3	32	5,55
1+34	INSPRASOL A 1093	140	2	1	0,5	110	3	32	11,1
1+34	INSPRASOL A 1094	140	2	1,25	0,5	110,5	4	31	0
1+34	INSPRASOL A 1095	140	2	1,25	0,5	110,5	2	33	5,55
1+34	INSPRASOL A 1096	140	2	1,25	0,5	110,5	2	33	5,55



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1+34	INSPRASOL A 1097	140	2	1,5	0,5	111	2	33	0
1+34	INSPRASOL A 1098	140	2	1,5	0,5	111	2	33	5,55
1+34	INSPRASOL A 1099	140	2	1,5	0,5	111	2	33	11,1
1+34	INSPRASOL A 1100	140	2	1,25	0,5	110,5	3	32	11,1
1+44	INSPRASOL A 1101	138	2	1,25	0,5	108,5	3	32	0
1+44	INSPRASOL A 1102	138	2	1,25	0,5	108,5	3	32	5,55
1+44	INSPRASOL A 1103	138	2	1,5	0,5	109	3	32	0
1+44	INSPRASOL A 1104	138	2	1,5	0,5	109	3	32	5,55
1+44	INSPRASOL A 1105	138	2	1,75	0,5	109,5	3	32	0
1+44	INSPRASOL A 1106	138	2	1,75	0,5	109,5	3	32	5,55
1+44	INSPRASOL A 1107	138	3	1,25	0,5	109,5	3	32	5,55
1+44	INSPRASOL A 1108	138	3	1,5	0,5	110	3	32	5,55
1+44	INSPRASOL A 1109	140	2	1,5	0,5	109	3	34	5,55
1+44	INSPRASOL A 1110	138	3	1,25	0,5	109,5	3	32	0
1+44	INSPRASOL A 1111	138	1	1,25	0,5	107,5	3	32	5,55
1+44	INSPRASOL A 1112	138	2	1,5	0,5	109	3	32	11,1
1+44	INSPRASOL A 1113	138	2	1,75	0,5	109,5	3	32	0



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1+44	INSPRASOL A 1114	138	2	1,75	0,5	109,5	3	32	5,55
1+44	INSPRASOL A 1115	138	2	1,25	0,5	108,5	3	32	11,1
1+44	INSPRASOL A 1116	138	1	1,5	0,5	108	3	32	5,55
1+44	INSPRASOL A 1117	140	2	1,75	0,5	111,5	3	32	11,1
1+44	INSPRASOL A 1118	140	2	1,75	1	112,5	3	32	0
1+44	INSPRASOL A 1119	140	2	1,75	1	112,5	3	32	5,55
1+44	INSPRASOL A 1120	140	2	1,75	1	112,5	3	32	11,1
1+44	INSPRASOL A 1121	138	3	1	0,5	109	3	32	0
1+44	INSPRASOL A 1122	138	3	1	0,5	109	3	32	5,55
1+44	INSPRASOL A 1123	138	3	1	0,5	109	3	32	11,1
1+44	INSPRASOL A 1124	140	3	1	0,5	111	3	32	0
1+44	INSPRASOL A 1125	140	3	1	0,5	111	3	32	5,55
1+44	INSPRASOL A 1126	140	3	1	0,5	111	3	32	11,1
1+44	INSPRASOL A 1127	140	3	1,25	0,5	111,5	3	32	0
1+44	INSPRASOL A 1128	140	3	1,25	0,5	111,5	3	32	5,55
1+44	INSPRASOL A 1129	140	3	1,25	0,5	111,5	3	32	11,1
1+44	INSPRASOL A 1130	140	3	1,25	0,5	111,5	3	32	0



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1+44	INSPRASOL A 1131	139	2	1,25	0,5	105,55	3	36	0
1+44	INSPRASOL A 1132	139	2	1,25	0,5	105,55	3	36	5,55
1+44	INSPRASOL A 1133	139	2	1,5	0,5	106	3	36	0
1+44	INSPRASOL A 1134	139	2	1,5	0,5	106	3	36	5,55
1+44	INSPRASOL A 1135	139	2	1,75	0,5	106,5	3	36	0
1+44	INSPRASOL A 1136	139	2	1,75	0,75	107	3	36	5,55
1+44	INSPRASOL A 1129	140	3	1,25	0,5	111,5	3	32	11,1
1+44	INSPRASOL A 1137	138	2	1,25	0,5	104,5	3	36	5,55
1+44	INSPRASOL A 1138	137	2	1,5	0,375	105,75	4	33	11,1
1+44	INSPRASOL A 1139	140	2	1,25	0,5	106,5	3	36	0
1+44	INSPRASOL A 1140	140	2	1,25	0,5	106,5	3	36	5,55
1+44	INSPRASOL A 1141	140	2	1,5	0,5	107	3	36	0
1+44	INSPRASOL A 1142	140	2	1,5	0,5	107	3	36	5,55
1+35,83	INSPRASOL A 1150	140	2	1,75	0,5	107,5	4	35	0
1+35,83	INSPRASOL A 1151	140	2	1,75	0,5	107,5	4	35	5,55
1+35,83	INSPRASOL A 1152	140	2	1,5	0,5	107	4	35	0
1+35,83	INSPRASOL A 1153	140	2	1,5	0,5	107	4	35	5,55



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1+35,83	INSPRASOL A 1154	140	2	1,25	0,5	106,5	4	35	5,55
1+35,83	INSPRASOL A 1155	140	2	1,8	0,5	107,6	4	35	0
1+35,83	INSPRASOL A 1156	139	2	1,75	0,5	106,5	4	35	11,1