ISOTONIC SODIUM CHLORIDE- biofleks isotonic sodium chloride sterile injection HAVER FARMA ILAC ANONIM SIRKETI

ADMINISTERED INTRAVENOUSLY ASEPTICALLY. Do not use if the solution is not clear or the bag is damaged. Please read the package leaflet. Consult your doctor right away if you have any unexpected effect. It is disposable. Partially used solutions should not be stored. Keep out of reach and sight of the children and store in the original package. Store at room temperature below 25°C. Sold with prescription only.

biofleks 100 mL 0.9 % ISOTONIC SODIUM CHLORIDE SOLUTION STERILE

Per 100 mL Sodium Chloride Water for Injection

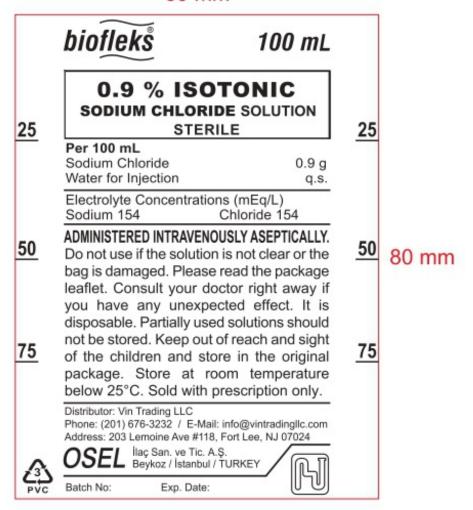
Electrolyte Concentrations (mEq/L)

ADMINISTERED INTRAVENOUSLY ASEPTICALLY. Do not use if the solution is not clear or the bag is damaged. Please read the package leaflet. Consult your doctor right away if you have any unexpected effect. It is disposable. Partially used solutions should not be stored. Keep out of reach and sight of the children and store in the original package. Store at room temperature below 25°C. Sold with prescription only. Distributor: Vin Trading LLC

Phone: (201) 676-3232 / E-Mail: info@vintradingllc.com Address: 203 Lemoine Ave #118, Fort Lee, NJ 07024 OSEL llaç San. ve Tic. A.Ş. Beykoz / İstanbul / TURKEY

100mL Bag

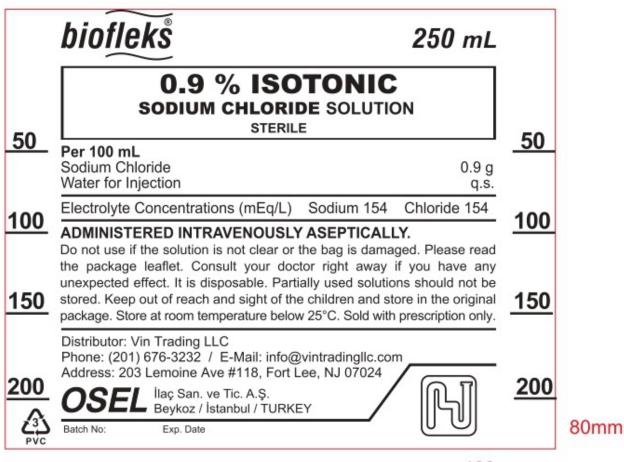
60 mm



Amerika Product Code: PVC - 254163/1

Graphic Designer: Bahar ATABAY

Regulatory Affairs Department	Regulatory Affairs Department	Production	Quality Control Laboratory	Quality Control Laboratory
			7	
Date:	Date:	Date:	Date:	Date:
			3	

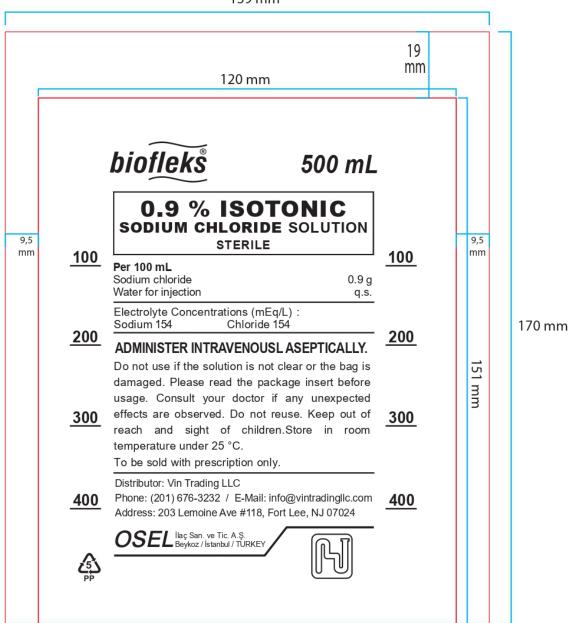


100mm

Amerika Product Code: 254164/1 Graphic Designer: Bahar ATABAY

Regulatory Affairs Department	Regulatory Affairs Department	Production	Quality Control Laboratory	Quality Control Laboratory
Date:	Date:	Date:	Date:	Date:
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139 mm



Amerika Product Code: PP - XXXXXX/0

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Regulatory Affairs Department	Regulatory Affairs Department	Production	Quality Control Laboratory	Quality Control Laboratory
Date:	Date:	Date:	Date:	Date:

220mm

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1000 mL

100	0.9 % ISOTONIC SODIUM CHLORIDE SOLUTION STERILE	<u>100</u>
200	Per 100 mL Sodium Chloride 0.9 g Water for Injection q.s.	200
300	Electrolyte Concentrations (mEq/L) Sodium 154 Chloride 154	300
400	ADMINISTERED INTRAVENOUSLY ASEPTICALLY. Do not use if the solution is not clear or the bag is damaged. Please read the package leaflet.	400
500	Consult your doctor right away if you have any unexpected effect. It is disposable. Partially used solutions	500
600	should not be stored. Keep out of reach and sight of the children and	<u>600</u>
700	store in the original package. Store at room temperature below 25°C. Sold with prescription only.	700
800	Distributor: Vin Trading LLC Phone: (201) 676-3232 E Mail: info@vintradingle.com	800



Amerika Product Code: 254166/1 Graphic Designer: Bahar ATABAY

Regulatory Affairs Department	Regulatory Affairs Department	Production	Quality Control Laboratory	Quality Control Laboratory
Date:	Date:	Date:	Date:	Date:

ISOTONIC SODIUM CHLORIDE

biofleks isotonic sodium chloride sterile injection

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:85184- 0001	
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS, IRRIGATION			

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)

SODIUM CHLORIDE

0.9 g in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 0590F0KO0R)				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:85184- 0001-1	100 mL in 1 BAG; Type 0: Not a Combination Product	01/01/2025	
2	NDC:85184- 0001-2	250 mL in 1 BAG; Type 0: Not a Combination Product	01/01/2025	
3	NDC:85184- 0001-3	500 mL in 1 BAG; Type 0: Not a Combination Product	01/01/2025	
4	NDC:85184- 0001-4	1000 mL in 1 BAG; Type 0: Not a Combination Product	01/01/2025	

Marketing Information					
Marketing Category Application Number or Monograph Citation Date Marketing Start Date					
Emergency Use Authorization		01/01/2025			

Labeler - HAVER FARMA ILAC ANONIM SIRKETI (365593526)

Registrant - HAVER FARMA ILAC ANONIM SIRKETI (365593526)

Establishment			
Name	Address	ID/FEI	Business Operations
HAVER FARMA ILAC ANONIM SIRKETI		365593526	manufacture(85184-0001)

Revised: 1/2025 HAVER FARMA ILAC ANONIM SIRKETI