



Comparison Table of UK product vs Imported product

	UK Licensed Product Product code FKE1324	Imported Product Product code 2B1324X
Bag label		
Product Name	Sodium Chloride 0.9% w/v Intravenous Infusion BP	0.9% Sodium Chloride injection, USP
Licence Status	UK registered product under Marketing Authorisation PL00116/0334	Unlicensed product imported with the agreement of the MHRA on a temporary basis under The Human Medicines Regulations 2012 (SI 2012/1916). Registered in the USA under NDC-0338-0049-004, NDA016677
Indications	Treatment of isotonic extracellular dehydration Treatment of sodium depletion Vehicle of diluent of compatible drugs for parenteral administration	Indicated as a source of water and electrolytes
Active	Sodium 154 mmol/L, Chloride 154 mmol/L	Sodium 154 mmol/L, Chloride 154 mmol/L
Excipients	Water for injections, EP	Water for injections, USP
Additional Information	pH 4.5 – 7.0 Osmolarity 308 mOsmol/L	pH 4.5 – 7.0 Osmolarity 308 mOsmol/L
Labelled Storage conditions	This medicinal product does not require any special storage conditions	Avoid excessive heat. Store at room temperature (25 °C) Note: Brief exposure up to 40 °C does not adversely affect the product. If stored at 2-8 °C do not use after 30 days even if returned to room temperature. 8 to 25 °C are ambient conditions.
Both products may be stored at ambient temperatures		
Container type	Viaflo (polyolefin/polyamide co-extruded plastic). Rigid port. Supplied in an overwrap. 10 bags per box (approx. 10kg)	Viaflex (polyvinyl chloride, di-ethyl hexylphthalate). Soft port. Supplied in an overwrap. 14 bags per box (approx. 14 kg)
Expiry Date format	MM/YYYY eg. 09/2021 = end September 2021	MON/YY eg. FEB 20 = end February 2020
Admin. port closure	Twist off port protector (white colour) 	Pull off port protector (blue colour)

Bag Labels

Baxter
Viaflo
FKE1324
1000 ml
Sodium Chloride 0.9% w/v
Intravenous Infusion BP
 pH 5.5 (approx) Isotonic
 Osmolarity 308 mOsm/l (approx)
Formula per 1000 ml
 Sodium Chloride 9 g
 Water for Injections
mmol per 1000 ml (approx)
 Sodium 154
 Chloride 154
IV administration
Read package leaflet before use
 Keep out of the reach and sight of children
 Do not remove from overwrap until ready for use
 Do not use unless solution is clear without visible particles, and container undamaged
 Do not reconnect partially used bags
Baxter Healthcare Ltd
 Thetford Norfolk IP24 3SE
 United Kingdom
POM 
 PL00116/0334
 PA167/8/15
 MA161/00403
 TH-35-01-526

 5 413760 137254
 LOT
 EXP

2B1324
 NDC 0338-0049-04
 DIN 00060208

0.9% Sodium Chloride Injection USP
1000 mL
 EACH 100 mL CONTAINS 900 mg SODIUM CHLORIDE USP pH 5.0 (4.5 TO 7.0) mEq/L SODIUM 154 CHLORIDE 154 OSMOLARITY 308 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR RX ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT
 VIAFLEX CONTAINER PL 146 PLASTIC
 BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC
 FOR PRODUCT INFORMATION 1-800-933-0303

Baxter
 BAXTER HEALTHCARE CORPORATION
 DEERFIELD IL 60015 USA
 MADE IN USA

Carton Labels

FKE1324
10 x 1000 ml (≈11.5 kg)
Sodium Chloride 0.9% w/v
Intravenous Infusion BP
Formula per 1000 ml **mmol per 1000 ml (approx)**
 Sodium Chloride 9 g Sodium 154
 Water for Injections Chloride 154
 Osmolarity 308 mOsmol (approx) pH: 5.5 (approx)
IV administration
Read package leaflet before use.
 Keep out of the reach and sight of children
 Do not reconnect partially used bags
Baxter Healthcare Ltd
 Caxton Way
 Thetford, Norfolk, IP24 3SE
 United Kingdom:
 PL00116/0334
 PA167/8/15
 MA161/00403

 TH-25-01-537
 LOT: XXXXXXXXXXXXW
 EXP: XX-XXXW

Baxter Healthcare Corporation
 Deerfield, IL 60015 USA
 Made in USA
2B1324X
 14-1000 ML VIAFLEX® CONTAINER
 0.9% SODIUM CHLORIDE INJECTION USP
 EXP FEB 20
 LOT Y279257

 (17)200200(10)Y279257

 (01)5030338001947
Baxter