Attachment 2

0.9% Sodium Chloride for Injection USP

Frequently Asked Questions

What is the replacement product?

The replacement product is 0.9% Sodium Chloride USP 1000ml supplied in Viaflex containers. These are imported from the United States of America.

Is the replacement product licensed in the UK?

No. This product has been imported as an unlicensed product with the agreement of the MHRA on a temporary basis under The Human Medicines Regulations 2012 (SI 2012/1916). This product is licenced in the USA and is registered by Baxter under NDC-0338-0049-004, FDA NDA016677.

How can I tell that this product is not licensed in the UK?

All units of the unlicensed product carry the product code 2B1324 on the bag label and 2B1324X on the carton label and so can be easily identified. There is no UK licence number (PL number) on the labelling. The Delivery Note also shows the product code and batch/lot number.

What is the difference between 0.9% Sodium Chloride for Infusion and Injection?

The UK product is labelled as Sodium Chloride 0.9% Intravenous Infusion and the USA product is called Sodium Chloride Injection. These products are equivalent and this is a difference in terminology between the UK and the USA. Both products can be used for fluid replacement by intravenous administration.

What are the differences between the UK and USA products?

a) The bag label contains different information as highlighted in the comparison document (Attachment 1).

b) All Viaflex containers are made of polyvinyl chloride (PVC). The plasticiser used in the manufacture of the PVC is Di (2-ethylexyl) phthalate (DEHP).

c) The port apparatus on the imported bags is soft with a blue pull off port protector. The port apparatus on the UK bags are rigid with a white twist off port protector. Because of the differences in the rigidity of the ports, the optimum technique for inserting the administration set into the port may be different to your normal practice. A poster is available to provide guidance on set insertion technique and will be widely circulated. Please contact servicecs@baxter.com if you require additional copies.

Where is the bar code on the bag?

The bar code on the imported 0.9% Sodium Chloride for Injection, USP is printed in white and is located at 90° to the label on the upper left-hand side of the bag. This bar code may not be recognizable within the UK. Please handle and check the products by the bag label and not the bar code.

Are the imported bags of 0.9% Sodium Chloride USP latex free?

Baxter can confirm we do not use natural rubber latex components in the manufacture of products in the Viaflex containers.

Are the imported bags of 0.9% Sodium Chloride USP DEHP free?

No. The bags are manufactured from polyvinyl chloride (PVC). This is a hard plastic and di-ethlyhexyl phthalate (DEHP) is used as a plasticiser.

Can a standard set be used with the imported bags of 0.9% Sodium Chloride for Injection USP?

Yes. The port is designed to accept giving sets which conform the International Standard ISO/FDIS 8536-4 Infusion equipment for medical use.

Is the surface of the primary bag inside the overwrap sterile?

Baxter Viaflex bags are sealed within their over pouch and then terminally sterilised using steam. Therefore, both the primary container and it's over pouch are considered sterilised. However, we cannot guarantee that the outer surface of the primary container will still be sterile when you open the over pouch as the overpouch may have been compromised during transport, storage and handling. Care should be taken when handling the products to minimise the risk of damage and the potential for contamination of the surface of the inner bag.

How should the imported bags of 0.9% Sodium Chloride for Injection USP be stored?

Please follow the label on the bags. The bags should be stored inside the overwrap in the same manner as other IV fluids are currently stored. There are no additional requirements necessary.

We use 0.9% Sodium Chloride 1000ml for aseptic compounding. Can I store the imported bags in the fridge?

The Viaflex container may be stored at 2-8°C but should not be used after 30 days even if returned to room temperature. If this causes concern, please contact Baxter Customer service or your local account manager. Baxter Customer Services: Tel: 01635 206060.

Note that the compatibility, stability, sterility and shelf-life of any drug addition to 0.9% sodium chloride USP 1000ml in Viaflex containers should be determined locally using the professional judgement of a suitably qualified person on behalf of the Trust. The shelf-life determined locally should not exceed 30 days at 2-8°C.

The imported bags are cloudy ('blushing') and/or have marks or a pattern on them. Is this normal?

Yes. During the sterilization process it is possible for some water vapour to become trapped within the Viaflex material of the bag. This gives the appearance of either a cloudy or milky plastic. This appearance is called 'blushing' and is normal. Over time this water vapour leaves the matrix of the plastic and the bag material reverts to a clear plastic. The bag material often clears quickly when removed from the overwrap.
During the sterilization process, due to the high temperature and pressure it is possible for the bags to take an imprint of the tray they lie on. This imprint appears only on one side of the bag (the side in contact with the tray). This is normal and has no impact on the integrity of the bag and does not affect its contents

There is moisture present inside the over pouch. Is this normal?

Water vapor transmission through plastic films is a well-recognized phenomenon which is facilitated in those circumstances where there is a distinct gradient in relative humidity. Since Viaflex containers are filled with water containing solutions, a 100% relative humidity is always present in the solution container. Moisture can transfer through the vinyl material into the envelope space and condense as beadlets.

Since the outside environment has less than 100% humidity, molecules of water will always move from the inside of the Viaflex container to the outside. The amount which is transmitted through the walls of the container is not sufficient to affect the concentration of the solution.

When the integrity of the over pouch and Viaflex container has been confirmed as recommended with each use, i.e. there are not leaks, excess moisture can be explained by the phenomenon described above.

The 'grab handless' of the carton box have been activated or 'popped'. Is it ok to use the bags inside?

You may notice that the handles on some of the cartons have been used or 'popped'. This has occurred when the boxes were stacked onto Euro size pallets for distribution within the UK. The bags inside the cartons will be unaffected by the activation of the carton handles, which are designed to facilitate handling.

How does the carton open?

There are perforations on the top of the carton to indicate the intended opening method. The photo below shows a carton which has been correctly opened.

What is the Pallet Factor for 2B1324X?

The product is configured in Euro pallets. The pallet factor is 35 boxes per pallet, with 14 units per box. The total units per pallet is therefore 490 units.

Can I have a certificate of analysis?

Yes. Please e-mail your request to servicecs@baxter.com, including details of the batch number(s) you require the certificate(s) for.

When will the next delivery arrive?

For details about specific orders and deliveries please refer to the local Commercial Business Manager or Customer Services on 0800 0289 881.

Are the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health & Social Care (DHSC) aware?

Baxter is working hard with the MHRA and the DHSC to ensure IV fluids continue to be supplied. The replacement product has been imported as an unlicensed product with the agreement of the MHRA on a temporary basis under The Human Medicines Regulations 2012 (SI 2012/1916). This product is registered by Baxter in the USA under NDC-0338-0049-004, NDA016677.

Where can I find more information?

For additional details regarding the use of the imported Viaflex bags of 0.9% Sodium Chloride USP please contact Baxter Medical Information.
Baxter Medical Information: https://mycustomercare.baxter.com

For details about supply please contact Baxter Customer service or your local account manager.
Baxter Customer Services: Tel: 01635 206060