

Flowfusor[®]

Instructions for Use

General

1. The Fresenius Flowfusor closure system is made up of three parts, designed for easy opening, spiking and pouring. This system provides a sterile field for spike insertion. the three parts are:

- (a) the **BREAKRING**, the white collar visible on unopened bottles. The function of the breakring is to remove the outer cap.
 - (b) the **OUTER CAP**, the translucent cap under the breakring. The outer cap is welded to the bottle, enclosing the sterile, spikeable inner cap.
 - (c) the **INNER CAP**, which is exposed when the outer cap is removed. The outer cap is both spikeable and removable, should pouring be required.
2. The bottle does not require venting when in use - the range of special Flowfusor giving sets have vented spikes.

3. Flowfusor solutions should be warmed to body temperature (37 °C) before use.

Visual Checking

1. Identify: formula, lot, and use by date.
2. Inspect the bottle for any obvious damage.
3. Inspect the solution. Do not use unless the solution is clear.

Spiking the Bottle

Note: The Flowfusor closure system provides a sterile field for spike insertion. Use aseptic techniques when opening and spiking.

1. Remove the outer cap. The breaking should feel slightly loose, if it does not, turn it clockwise until it does. Using a sharp turning motion, screw the breakring anti-clockwise. The outer cap and breakring assembly will snap off, exposing the sterile inner cap.
2. Using the appropriate Flowfusor giving set, as instructed on the set, push the spike into the recess on the top of the inner cap. Push in until the collar beneath the finger guard touches the top surface of the inner cap. The breakthrough part in the centre of the inner cap will remain attached to the cap.
3. Hang the bottle as necessary using the hanging tab on the bottom of the bottle.

Pouring from Flowfusor

1. Snap off the outer cap as in 1 above.
2. Unscrew the inner cap and pour.



Fresenius Kabi Limited, Runcorn, Cheshire, WA7 1NT, U.K.

01-59-06-001A

MASTER ARTWORK/LABEL SPECIFICATION

Halden article number:	NA
Label specification number:	01-59-06-001A
Pharma code:	NA
Code line:	NA
Colour coding:	Black
Typeface:	Antique Olive, Frutiger
Size:	A5 (210 x 148 mm)
GLS:	NA

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User Information

General

Unless otherwise indicated, the information below relates to all solutions in the Flowfusor range.

Recommended Clinical Indications, and Route of Administration

1. For irrigation and lavage during surgery and post-operative care, especially in urology.
2. For irrigation only.

Recommended Doses and Dosage Schedules

1. Adults and Children

The volume and rate of irrigation will depend upon the judgement of the surgeon.

2. Elderly

Care should be taken to avoid circulatory overload, particularly in patients with cardiac and renal insufficiency.

Contraindications

Purisole only

1. Patients with a history of intolerance to fruits may have hereditary fructose intolerance. Because sorbitol is metabolised to fructose in the liver, a fructose intolerance test must be carried out on these patients. Purisole is contraindicated in these patients if this test is not performed.
2. Purisole is contraindicated in infants and children.
3. Purisole may be contraindicated in patients where there is methanol intoxication.

Undesirable Effects

Fluid overload, electrolyte disturbance and cerebral oedema may occasionally occur.

Water for Irrigation Only

Haemolysis may occur if significant amounts are absorbed.

Use in Pregnancy and Lactation

The safety of Flowfusor solutions during pregnancy and lactation has not been established, but is not considered to constitute a hazard. However, their use should be avoided during the first three months pregnancy.

Other Special Warnings and Precautions

1. Store at 2°-25 °C.
2. Do not use unless the solution is clear and container and seal are intact.
3. Discard unused portion
4. For irrigation only, not for injection.

Overdose

Overdose may lead to fluid overload, electrolyte disturbances and possibly cerebral oedema. Treatment should consist of discontinuing irrigation and employing symptomatic and supportive measures, including correction of fluid and electrolyte balance.

Manufactured by:

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Halden, Norway



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