



## PROGRESSION IS PRE-FILLED

Up to now the only Patent Blue V product available is an unlicensed glass ampoule.

**PATENT BLUE V  
GLASS AMPOULES ARE:**

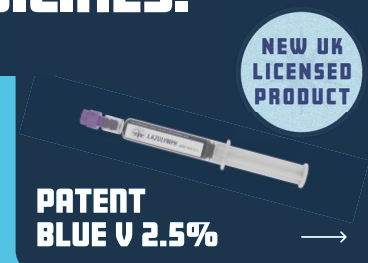
**UNLICENSED  
EXPENSIVE  
LINKED TO SHARPS INJURIES  
COMPLEX TO PREPARE  
INEFFICIENT**

Ways to use these important medicines for operating theatre teams<sup>3-5</sup>

## IT'S TIME FOR BETTER ESSENTIAL MEDICINES.

Further information and a copy of the  
'Instructions For Use' can be found at:  
**[www.progressionisprefilled.com](http://www.progressionisprefilled.com)**

### OUR PRODUCTS



# PROGRESSION IS PRE-FILLED

with the most advanced Patent  
Blue V presentation yet

**UPGRADE TO THE NEW STANDARD OF  
PATENT BLUE V**



The **NEW Flexipharm Trading Patent Blue V 2.5% plastic Pre-Filled Syringe** is specifically designed and **licensed for use as a surgical dye**, for a safer, cheaper, and simpler Patent Blue V marker for surgery that protects and maximises the efficiency of your theatre teams.<sup>1-5</sup>

## COMPARED TO GLASS AMPOULES, FLEXIPHARM TRADING PATENT BLUE V 2.5% PLASTIC PRE-FILLED SYRINGE HAS THREE CLEAR ADVANTAGES:

### SAFER

Under the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013, hospitals have a legal obligation to use safer sharps where practical as a strategy to protect staff and patients. Plastic Pre-Filled Syringes are a safer sharp.<sup>2</sup>

Over 35% of sharps injuries occur in the operating theatre and up to 1 in 3 sharps injuries are caused by the glass spikes formed when opening ampoules (20–32%).<sup>3,4</sup>

The Flexipharm Trading Patent Blue V 2.5% plastic Pre-Filled Syringe offers a safer sharp option, eliminating the risk of injury associated with opening and extracting drug from glass ampoules.<sup>2</sup>

### CHEAPER

Glass ampoules waste NHS budgets through unnecessary risk of sharps injuries and the need for sterilisation and filter needles.<sup>4-6</sup>

Sharps injuries cost each NHS trust **£500,000 per year** in legal fees.<sup>6</sup>

Flexipharm Trading Patent Blue V 2.5% plastic Pre-Filled Syringe is **£90–100/pack cheaper** than the unlicensed glass ampoule **AND** eliminates the unnecessary costs of consumables needed to extract dye from an ampoule.<sup>5</sup>

### SIMPLER

Patent Blue V glass ampoules have no UK regulatory approval and are an unlicensed medicine, creating avoidable administration around ordering and checking product when delivered, and preparation work for staff, including documenting use of an unlicensed medicine.<sup>5,7,8</sup>

Glass ampoules require 10+ steps to prepare, most with a risk of sharps injury, which can lead to delayed or cancelled operations.<sup>6,9</sup>


Flexipharm Trading Patent Blue V 2.5% plastic Pre-Filled Syringes are a direct clinical alternative that are UK licensed products, individually sterile wrapped with just one step to have dye ready for use.<sup>1</sup>



## NHS HOSPITALS ORDER TODAY FROM MAWDSLEYS

 0844 736 9016

 Email

 Online

Product name	Patent Blue V 2.5%, 2ml, individually sterile wrapped Pre-Filled Syringe
Mawdsleys Description	PATENT BLUE V PFS 2.5% 2ML(50MG/2ML)
Supplier	Flexipharm Trading Limited
Pack size	5 x 2ml Pre-Filled Syringes
List/Public price per pack	£240.00*
PIP code	1265545
EAN code	08052742102582

\*hospital/contract price available

## REFERENCES

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# INSTRUCTIONS FOR USE

## PATENT BLUE V 2.5%

### STERILE PYROGEN-FREE SOLUTION MARKER FOR SURGERY

#### NAME OF MEDICAL DEVICE:

Patent Blue V 2.5% marker for surgery.

#### QUALITATIVE AND QUANTITATIVE COMPOSITION:

Patent Blue V Sodium Salt 25 g - Sodium Hydroxide q.s. pH 9.5 - Water for injections q.s. to 1000 mL.

#### TYPE OF DEVICE:

Sterile pyrogen-free solution - Class IIa.

#### USE:

Patent Blue V is a vital dye suitable for the marking of sentinel lymph nodes in the breast cancer and in the intraoperative sentinel lymph nodes mapping in patients with colon cancer. It is also used in the preoperative lymphoscintigraphy for the biopsy of sentinel lymph nodes in the melanoma.

#### CONTRAINDICATIONS:

Hypersensitivity to Patent Blue V Sodium Salt.

**WARNING:** The device should not be administered during pregnancy. Avoid the use during the lactation and in pediatric patients, because the related studies are not available.

#### SIDE EFFECTS:

Patent Blue V Sodium Salt can cause what follows:

- hives, itch, rash;
- transient hypotension, bronchospasm / laryngospasm;
- rare cases of anaphylaxis, anaphylactic shock and angioneurotic edema.

#### WARNINGS AND PRECAUTIONS FOR USE:

Patent Blue V can also cause severe allergic reactions. Before use, check the patient's allergies and intolerances. Anesthesiologists and surgeons should carefully consider the onset of the first symptoms of an allergic reaction. They should also ensure the availability of personnel and equipment necessary to treat a possible allergic reaction, supervising for at least 1 hour from the time of administration, as there could be a possible delay of the onset of an adverse reaction. After the injection a bluish discoloration on the surrounding skin, that normally disappears within 24-48 hours, may occur. In the case of an intradermal injection the staining skin may persist for a long time. The dye is eliminated in 24-48 hours after the injection through the urine, strongly colored, but also through the bile.

#### INSTRUCTIONS FOR USE:

**To be used with needle with Luer Lock connection:**

***Intraoperative sentinel lymph nodes mapping in patients with breast cancer.***

The vital dye may be injected by subdermal, intradermal, periareolar, peritumoral or intratumoral route, although this last route is rarely used, because it requires the administration of high volumes of dye, given the paucity of lymphatics within the tumor mass.

The amount to be used depends on the route of administration.

- By subdermal route you should inject (approximately) 0.2-0.4 ml of Patent Blue V.
- By peritumoral route you should inject larger volumes in two or more peritumoral points: (approximately) 1-2 ml for tumors in the upperouter quadrant; (approximately) 2-3 ml for tumors at the confluence of external or internal quadrants; (approximately) 3-4 ml for tumors in lower quadrants.

#### ***Intraoperative sentinel lymph nodes mapping in colon cancer in early stage***

A total amount of less than 2 ml of vital dye Patent Blue V is injected into the peritumoral region, at the four cardinal points, in the subserosal area so as to allow the identification of the first 4 sentinel nodes.

#### ***Preoperative identification of sentinel lymph nodes in melanoma***

Make peri-lesional intradermal injections of (approximately) 0.5-1 ml of Patent Blue V 20 minutes prior to skin incision.

#### EXPIRY DATE:

Check the expiry date printed on the container. The expiry date refers to the product properly stored in an unopened package. Caution: Do not use the product after the expiry date.

#### SPECIAL PRECAUTIONS FOR STORAGE:

Store in its original packaging to protect the product from light. No special storage conditions as regards temperature. Do not freeze. Do not use if the container is damaged. The solution should be used for a single, uninterrupted administration only and any residue should be discarded to prevent the risk of contamination due to loss of sterility.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

#### SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING OF THE DEVICE:

Any unused part of the device and waste material deriving from it should be disposed of in accordance with local legislation in force.

#### SERIOUS INCIDENT REPORTING:

**The user and/or patient are recommended to report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.**

#### MEDICAL DEVICE FORM AND CONTENT:

Prefilled syringe of 2 mL with a protective wrapping.

#### MANUFACTURER:

S.A.L.F. S.p.A. LABORATORIO FARMACOLOGICO  
Via Marconi, 2 - 24069 Cenate Sotto (BG) Italy

#### DATE OF REVISION:

18-01-2023