



20 August 2026,

Direct Healthcare Professional Communication on the association of Patent Blue Violet (Patent Blue V) with serious allergic reactions

Dear Healthcare Professionals,

This letter is to inform you of important safety information on the use of blue dye Patent Blue V.

Summary

- A number of serious allergic reactions, including anaphylaxis, have occurred in patients receiving Patent Blue V.
- Patent Blue V does not carry a license for marketing in the UK.
- Surgeons are reminded of the risk of serious allergic reactions and are advised to have competent personnel and emergency facilities available for at least 1 hour following administration of Patent Blue V, as delayed reactions may occur.

This issue was discussed at the UK national Pharmacovigilance Expert Advisory Group of the Commission on Human Medicines.

Further information on the safety concern

Patent Blue V is used in lymphatic mapping for sentinel lymph node biopsy (SLNB). The product does not carry a license for marketing in the UK.

Allergic reactions are known to occur with the use of Patent Blue V and a similar substance, isosulfan blue. On the basis of a clinical study (the ALMANAC trial) and a follow-up program (the NEW START program), serious allergic reactions with Patent Blue V during SLNB were estimated at an incidence rate of 0.1%. Since 2007, a total of 554 cases of allergic reactions were reported to the Medicines and Healthcare Products Regulatory Agency; 516 of these cases were serious cases with allergic reactions. With increasing usage of Patent Blue V in the UK, the number of serious allergic reactions reported to us is also expected to rise.

This issue was discussed at the UK national Pharmacovigilance Expert Advisory Group of the Commission on Human Medicines in November 2011. The Group advised that emergency measures should be available to treat patients that may experience allergic reactions or anaphylaxis. This DHPC was initially launched in 2012 and updated in 2022, and again in 2026.

Surgeons are reminded to remain aware of the risk of serious allergic reactions, including anaphylaxis, associated with the use of Patent Blue V. Please remember to have competent personnel and emergency facilities available for at least 1 hour after administration of Patent Blue V (as delayed reactions may occur).

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact

If you wish to contact Guerbet Laboratories Ltd. for further information, please use the details below:

Tel: +44 (0) 121 733 8542

Fax: +44 (0) 121 733 3120

Out-of-hours **emergency** number: +44 (0) 7824 602 555.

Email:

Common mailbox for consumer queries: uk.info@guerbet.com

For Adverse Events, Product Quality Complaints and/or Medical Information Enquiries, please contact UK_LRPPV.guerbet@apcerls.com

Name	Date and Signature (signed by/on behalf of)
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Philippe BOURRINET, PharmD Senior Vice-President Development, Medical & Regulatory Affairs Group Responsible Pharmacist	Signé par : Philippe Bourrinet  Nom du signataire : Philippe Bourrinet Motif de la signature : J'approuve ce document Heure de signature : 21-Aug-26 00:26:50 PDT AF605EAAE4B64954982B85F614957E04