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Registered in England
No. 02940474

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

Dear Doctor,

This letter is to inform you of important new safety information on the use of the 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 licence 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 licence 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 58 cases of allergic

reactions were reported to the Medical and Healthcare products Regulatory Agency; 26 of these were serious 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.

The 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.

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 report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card Scheme online at www.yellowcard.gov.uk, stating the seriousness of the reaction. Alternatively, prepaid Yellow Cards are available through electronic download on the MHRA website (<http://yellowcard.mhra.gov.uk/downloads/>) and at the back of the British National Formulary (BNF).

Company contact

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

Tel: 0121 733 8542

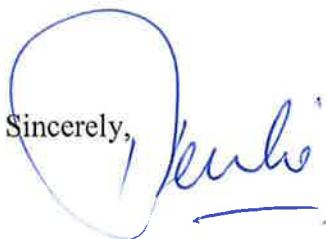
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Sincerely,



Dr Pierre Desche

Vice-President Medical & Regulatory Affairs