



Advancing Female Pelvic Medicine
and Reconstructive Surgery

Indigo Carmine Shortage

How is indigo carmine used in female pelvic reconstructive surgery?

Indigo carmine (Indigotindisulfonate sodium) is commonly used to help assess ureteral patency. It is given intravenously and largely renally excreted. Urine is colored blue and is therefore more easily visualized cystoscopically as blue efflux is noted from the ureteral orifices. In patients with normal renal function and adequate hydration, the dye is visible after approximately 10 minutes, having a half-life of 4-5 minutes. Because of its molecular size, it is largely excreted rather than reabsorbed, and retains its blue color as it passes through the body.^{1,2,3} Indigo carmine can have a mild pressor effect and should be used with caution in patients with cardiac or vascular disease.¹

How is indigo carmine supplied and why is there a current shortage?

Indigo carmine is supplied in 5 ml ampules of 8mg/mL. There have been two suppliers in the United States: Akorn and American Regent. Akorn has discontinued manufacturing of indigo carmine with no plan to resume. According to the American Society of Health System Pharmacists and the FDA, this decision was due to an inability to obtain an active ingredient.^{4,5} American Regent plans to continue manufacturing indigo carmine based on component availability. They recommend checking their website, americanregent.com, for availability.

What are the alternatives to indigo carmine?

There is no other dye that can definitively replace indigo carmine, but others may be used to assist in cystoscopically assessing ureteral patency.⁴

Methylene blue can be used intravenously. However this alternative has some risk. Methylene blue is variably metabolized so may not always be visualized in the urine and cannot be used in pregnant patients or those with glucose-6-phosphate dehydrogenase deficiency.² It is also a monoamine oxidase inhibitor.

While it is used to treat methemoglobinemia, it can also cause methemoglobinemia when administered in high doses. Methylene blue is supplied in 1ml ampules of 10mg/mL and administered as 0.1-0.2ml/kg injected intravenously slowly over several minutes.⁷

Patients may be given phenazopyridine 200mg orally several hours prior to a procedure to stain the urine orange.

Indigo carmine is a dye whose unique properties make it useful in assessing ureteral patency. This is crucial in female pelvic reconstructive surgery. The rate of ureteral injury in gynecologic surgery ranges from 0.6-11% depending on the specific procedure.⁸⁻¹⁰ Unidentified ureteral injury can lead to significant morbidity, even complete loss of ipsilateral renal function. Therefore it is crucial to have a standard method of assessing ureteral patency, and this has generally been via the administration of indigo carmine intravenously. AUGS supports every effort to make indigo carmine available.

References:

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