



Batch DM 998

Case report

In March 2003 the pharmacist of this hospital warned the anesthesia department that the batch of Naropin® numbered DM 998 was recalled by the producer because of improper labeling. In fact, the side of the cardboard boxes containing plastic vials of 1% ropivacaine indicated a 0.75% concentration ; on the top of the boxes the correct concentration was printed on the classical green color band (photograph in the middle) ; the vials indeed contained 1% ropivacaine. In the hospital the ensuing quest for the faulty batch increased the general level of vigilance towards the drug and its labeling.

One week later the trainee on duty was called in the middle of the night to perform an epidural for labor. Double-checking the vial a nurse presented to him he found it to be a 1% solution of Naropin® instead of the usual 0.2%. To his surprise, both dosages featured labels of the same color (photograph on the left). The procedure was otherwise uneventful, using a 0.2% solution. Concerned, however, by this intriguing security event, he duly reported it the same morning. The enquiry conducted by the pharmacist disclosed that the batch # DM998, after returning to the producer, had come back with a makeshift correction of the faulty indication on the boxes (red circle and arrow in the middle photographs). It was then discovered that all 1% vials inside the boxes had black labels instead of their classical green ones. A call to the producer taught us that a color change had been decided at the international level in their company and was to be definitive ; all concentrations now wore black labels. Neither anesthesiologists nor pharmacists had been given prior notice of this change in Belgium. As an emergency measure the pharmacists of the reporting hospital immediately put green stickers on the outside of the plastic blisters containing the 1% vials (photograph on the right).

Discussion

Naropin® is widely used for labor analgesia in the involved maternity ward. The 0.2% dosage is used for vaginal births and 1% for caesarean section. Up to this episode the different concentrations came with labels of different colors : black for 0.2% and green for 1%. A 0.75% solution also existed with purple labels. Local safety guidelines excluded 1% Naropin® vials from labor rooms and restricted their distribution to the C-section operating theatre. Workers transporting drug boxes and other supplies are not medically-trained people ; unsurprisingly they sort anesthesia vials by shape and color when refilling stocks. Changing the color of the labels immediately led to failure to identify vials and to distribution errors : it actually broke through all local safety procedures existing upstream of the ultimate check prior to injection. In the absence of advance notice, it took a particularly watchful physician to avoid an erroneous injection in the present case.

Color codes are very important to identify medical products not only because of drugs being set up by non-medically trained people but also because they minimize the risk for errors at the bedside, especially under stressful or emergency circumstances. Changing labels without prior notice, especially re-labeling stronger concentrations with the color previously identifying the weakest one, shows at

best a profound lack of understanding of how products are used and provoked a serious breach in patient safety.

Pharmaceutical companies should not design ampoules and containers of injectable drugs merely to allow their identification, they should rather strive for their *immediate recognition*.

Answer to Acta Anesthesiologica Belgica

First AstraZeneca would like to express its regrets for the coincidence of two independent changes in the Ropivacaine pack.

AstraZeneca would however like to separate these unfortunate incidences for further explanation. The first one concerned a printing error in the description of the formulation of Naropin 10 mg/ml on the outside carton box and the second case a change in colour labelling of Naropin poly-ampoules.

1. The error in the formula

In the formula, printed on the side face of the carton, Ropivacaine. Hydrochloride. 150 mg was mentioned instead of 200 mg.–aqua ad 20 ml.

The dosage was correct on the main face of the carton in the dedicated place for name and dosage (inside a coloured band) and also on the primary pack, the blister paper as well as on the ampoule and so there was ample information not to lead to misuse.

Upon being informed of this error, AstraZeneca immediately took the decision to inform all its customers and started a recall of the delivered cartons.

The remaining stock of that batch in the warehouse was immediately corrected and new artwork was prepared for future supplies.

The Inspector of Pharmacy was informed of the recall and approved the rework procedure consisting of overprinting the error in the formula.

2. The standardisation of colours on the ampoules (applicable for 7,5 mg/ml and 10 mg/ml)

The decision to remove colours from the primary pack was taken by the global production unit for technical reasons. It was identified that the colours could be damaged during the sterilisation process and could thus compromise the readability of the text on the ampoule label.

This decision was also part of a harmonisation process since Belgium was one of the few countries with a colour differentiation for Naropin poly-ampoules.

Unfortunately, as the use of colours is not part of the registered file, i.e. not a legal requirement, the manufacturing team did not immediately inform the implementation date of this change to ourselves in Belgium.

Normally we would inform hospitals and anaesthetists of any changes, before releasing new or changed batches onto the Belgian market.

AstraZeneca accepts the view of the author that products should be presented in a way to avoid any possible misuse. Supporting this view, AstraZeneca Belux has agreed with our manufacturing colleagues to return to the colour identification process.

This has been made possible after examination of the technical problems where it was concluded that by changing slightly the PMS reference colour code the issue could be resolved. A colour differentiation between dosages is helpful but can never be a substitute for correct text reading of the dosage.

Implementation for new production runs will take a couple of months and in the mean time we will fix a small coloured product label on the outside (transparent face) of the blister of the NAROPIN 7.5 mg/ml and 10 mg/ml presentation.

AstraZeneca aims to ensure that any of its products with a wide range of dosages have a clear differentiation in order to avoid any misuse.

Finally AstraZeneca would like to thank the author for the alertness and willingness to inform the company of this incidence allowing us to take immediate action, thus preventing potential accidental misuse.