UKM MEDICAL CENTRE

Pharmacy Bulletin

EDITION 3 / 2011 VOLUME 12, ISSUE 3

UPDATES ON THE USE OF CEFTRIAXONE (ROCEPHINE®) IN NEONATES

In September 2007, FDA issued a warning letter regarding the concomitant use of Ceftriaxone with calcium containing solutions. This warning came after Roche, manufacturer of Ceftriaxone provided 5 post-marketing reports of neonatal deaths related to the interaction between Ceftriaxone and calcium containing products. In 4 neonates, ceftriaxone was co-administered with calcium-containing fluids using the **same infusion line** while the 5th neonate, ceftriaxone and calcium gluconate were administered by different ROUTES and at different TIMES. 2 autopsies found evidence of crystalline material in the renal and pulmonary vasculature. In the 3rd neonate, there was evidence of precipitation in the IV tubing and the neonate's death occurred soon after the crystalline material was injected.

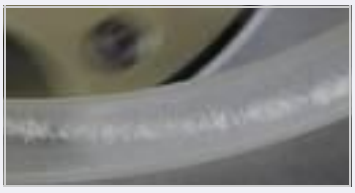
In 2009, at the request of FDA, Roche conducted two in vitro studies to assess the potential for precipitation of ceftriaxone-calcium when ceftriaxone & calcium-containing products are mixed in vials & infusion lines. These 2 in vitro studies were conducted in neonatal & adult plasma to assess the potential for precipitation of ceftriaxone-calcium using various ceftriaxone and calcium concentrations, including concentrations in excess of those achieved in vivo. Based on the results from these studies, FDA has the following recommendations :

In 2007

Recommendations :

- Ceftriaxone should not be administered concurrently with calcium-containing solutions or products in newborns because of the risk of precipitation of ceftriaxone-calcium salt.
- Ceftriaxone must not be mixed or administered simultaneously with calcium-containing solutions or products, even via different infusion lines.
- Concomitant administration of Ceftriaxone and calcium-containing solution/product must not be administered within 48hours after the last dose of Ceftriaxone, even via different infusion lines.

Pictures of precipitation of drug



UPDATED !!

UPDATED Recommendations :

- Concomitant use of ceftriaxone and intravenous calcium containing products is contraindicated in neonates (<28 days of age). Ceftriaxone should not be used in neonates (<28 days) if they are receiving (or are expected to receive) calcium containing intravenous products.
- In patients > 28 days of age, Ceftriaxone & calcium-containing products may be administered sequentially, provided the infusion lines are flushed thoroughly with a compatible fluid.
- Ceftriaxone must **NOT** be administered simultaneously with intravenous calcium-containing solutions via Y-site in any age group.

FDA is reiterating 3 of the previous recommendations in 2007 :

- Use of Ceftriaxone in neonates <28 days who need parenteral nutrition or calcium-containing IV products.
- Simultaneous administration of Ceftriaxone and calcium -containing IV product via an IV tubing Y-site, to patients of any age.
- Reconstitution or mixing of ceftriaxone with any calcium -containing product, such as Ringer's or Hartmann's solution or parenteral nutrition containing calcium, because particulate formation can result.

No reported cases when :

- IM Ceftriaxone is given simultaneously with oral or IV calcium supplement.
- IV Ceftriaxone is given simultaneously with oral calcium supplement.

For.Your.Drug.Information.

DILUTION FOR DOPAMINE 40mg/ml INFUSION

Drug Information Centre has been receiving calls on the dilution of dopamine for infusion from different wards.

Below are the recommendations according to wards. [As discussed with Anesthetist]

For **GENERAL** wards;

For patients < 60kg : [3 x weight] in 50ml D5%.

For patients >60kg, formula is same as above but with a maximum concentration of 4mg/ml

For **INTENSIVE CARE** wards,

For patients > 60 kg : 200mg in 50ml D5% . Please use **CENTRAL** line only.

Note : The double strength dilution ie [6 x weight] in 50ml is **NO** longer recommended due to confusion of the dilution & maximum concentration.

Reference :

1. HKL ICU Handbook
2. UK CPA Critical Care Group "Minimum infusion volumes for fluid restricted critically ill patients 3rd Edition

STREPTOKINASE 1.5 million IU/vial DILUTION FOR PULMONARY EMBOLISM

DOSE :

Loading dose **250,000 iu** over 30 minutes then maintenance dose 100,000 iu per HOUR for 12-72 hours (with monitoring of clotting parameters)

DILUTION :

Reconstitute each vial (1.5 MEGA iu) with **5ml NS**

- Then dilute further with NS/D5% up to **150 ml**
- [Final Concentration = **10,000 iu/ml**]

ADMINISTRATION :

- Loading Dose : Run **25ml** (250,000 iu) over **30 min**
- Maintenance Dose : Run **10ml/hr** (100,000 iu/HOUR)

A Publication of :
Drug Information Centre
Pharmacy Department,
UKM Medical Centre

Editors :

Izyan Diyana Ibrahim
izyandi@ppukm.ukm.my
03-91455415

Michelle Tan Hwee Pheng
hptan@ppukm.ukm.my
03-91455401

Pharmacy's website : **http://pharmacy.hukm.ukm.my/**

JKTU MEETING 1/2011

The next Drugs & Therapeutics Meeting will be held as follows :

- 25th MARCH 2011
- Friday
- 3 PM
- Ground Floor Meeting Room, Pharmacy Dept.