



DRS/MC/IEA.79

21 January 1999

Information Exchange System**Alert No. 79****Glucose ampoules recalled (Mini-Plasco®) – mislabelling: found to contain harmful potassium chloride**

Belgium. The General Pharmaceuticals Inspectorate has issued a Rapid Alert concerning ampoules containing potassium chloride (KCl) solution that have been mislabelled as Mini-Plasco® Glucose 5%/10 ml sterile solution for injection. Two premature infants have died after being injected with this product.

The manufacturer and distributor, B. Braun, reports that one batch is implicated (batch number: **97H21C** - Belgium, and **7344C16** - Germany, Expiry date **01/2001**). The marketing authorization number in Belgium is: **170 IS 211 F 12**.

B. Braun stated that they had produced 135,000 ampoules in this batch and that batch 97H21C has been distributed in Belgium, Luxembourg, the Slovak Republic and Germany.

This alert is being issued so that other Member States can ensure that the product is not causing the same safety problems in another country.

Reference: EU/EEA Rapid Alert, General Pharmaceuticals Inspectorate, Ministry for Social Affairs, Public Health and the Environment, Brussels, 20 January 1999.

