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CYANOKIT® 2.5 g

HYDROXOCOBALAMIN

Powder for solution for infusion

Treatment of known or suspected cyanide poisoning

STORM - 03/2009

CYANOKIT® 2,5 g powder for solution for infusion. PHARMACEUTICAL FORM: Dark red crystalline powder for solution for infusion (IV): 2 vials (each one contains 2.5 g powder) + 2 sterile transfer devices + 1 sterile intravenous infusion set + 1 sterile short catheter for administration to children. **COMPOSITION*:** After reconstitution with 100 ml of diluent, each ml of the reconstituted solution contains 25 mg of hydroxocobalamin. **INDICATIONS:** Treatment of known or suspected cyanide poisoning. Cyanokit® is to be administered together with appropriate decontamination and supportive measures. **POSOLOGY AND METHOD OF ADMINISTRATION*: Initial dose:** Cyanokit® is administered as an intravenous infusion over 15 min. *Adults:* the initial dose of Cyanokit® is 5 g. *Paediatric patients:* the initial dose is 70 mg/kg body weight not exceeding 5 g.

Body weight in kg	5	10	20	30	40	50	60
Initial dose in g	0.35	0.70	1.40	2.10	2.80	3.50	4.20
in ml	14	28	56	84	112	140	168

Subsequent dose: Depending upon the severity of the poisoning and the clinical response, a second dose may be administered by intravenous infusion.The rate of infusion for the second dose ranges from 15 minutes to 2 hours based on patient condition. *Adults:* 5 g. *Paediatric patients:* 70 mg/kg body weight not exceeding 5 g. **Maximum dose:** *Adults:* 10 g. *Paediatric patients:* 140 mg/kg not exceeding 10 g. **Renal and hepatic impairments:** Cyanokit® is administered as emergency therapy in an acute, life threatening situation only and no dosage adjustment is required in these patients. **CONTRAINDICATIONS:** None. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE*: Treatement of cyanide poisoning must include immediate attention to airway patency, adequacy of oxygenation and hydration, cardiovascular support, and management of seizures. Treatment decisions must be made on the basis of clinical history and/or signs and symptoms of cyanide intoxication.** - Smoke inhalation: Before Cyanokit® is administered, it is recommended to check affected persons for the presence of exposure to fire smoke in an enclosed area, soot present around mouth, nose and/or oropharynx, altered mental status. Hypotension and/or a plasma lactate concentration ≥ 10 mmol/l are highly suggestive of cyanide poisoning. In the presence of the above signs, treatment with Cyanokit® must not be delayed to obtain a plasma lactate concentration. - Known hypersensitivity to hydroxocobalamin or vitamin B12 must be taken into benefit-risk consideration before administration of Cyanokit®. - Transient, generally asymptomatic, increase in blood pressure may occur with a maximal increase toward the end of infusion. - Effects on blood cyanide assay. Recommended to draw the blood sample before intiation of treatment with Cyanokit®. - Interference with burn assessment due to a red colouration of the skin. However skin lesions, oedema, and pain are highly suggestive of burns. - Interference with laboratory tests (e. g. clinical chemistry, haematology, coagulation and urine parameters) because of hydroxocobalamin's deep red colour. Caution is required when reporting and interpreting laboratory results. - Use with other cyanide antidotes: has not been established; they must not be administered concurrently in the same intravenous line. **INTERACTIONS* PREGNANCY AND LACTATION*:** There are no adequate data from the use of hydroxocobalamin in pregnant women and the potential risk for humans is unknown. However, taken into account that no more than two injections of hydroxocobalamin are to be administered, the potentially life threatening condition, the lack of alternative treatment, hydroxocobalamin may be given to a pregnant woman. Health care professionals are requested to promptly report the exposure during pregnancy to the Market Authorisation Holder and to carefully follow-up on the pregnancy and its outcome. Because hydroxocobalamin will be administered in potentially life-threatening situations, breast-feeding is not a contraindication. **UNDESIRABLE EFFECTS*:** *The most frequents:* reversible red colouration of the skin and mucous membranes, marked dark red colouration of the urine. *Reported in association with Cyanokit® use, without frequency estimations:* artificial elevation or reduction in the levels of certain laboratory parameters; ventricular extrasystoles; decrease in the percentage of lymphocytes; memory impairment, dizziness; eye disorders such as swelling, irritation, redness; pleural effusion, dyspnoea, throat tightness, dry throat, chest discomfort; abdominal discomfort, dyspepsia, diarrhoea, vomiting, nausea, dysphagia; pustular rashes (face and neck); transient increase in blood pressure; hot flush; headache, injection site reaction, peripheral oedema; allergic reactions including angioneurotic oedema, skin eruption, urticaria and pruritus; restlessness. **OVERDOSE*:** Treatment is directed to the management of symptoms. **PHARMACODYNAMIC PROPERTIES*:** Antidote, ATC code: V03AB33. *Mechanism of action:* Each hydroxocobalamin molecule can bind one cyanide ion by substituting the hydroxo ligand linked to the trivalent cobalt ion to form cyanocobalamin, a stable, non-toxic compound that is excreted in the urine. **PHARMACOKINETIC PROPERTIES*. PRECLINICAL SAFETY DATA*. INCOMPATIBILITIES*:** Cyanokit® must not be mixed with other medicinal products except the recommended diluant - No simultaneous administration of hydroxocobalamin through the same intravenous line with the following drugs: diazepam, dobutamine, dopamine, fentanyl, nitroglycerine, pentobarbital, phenytoin sodium, propofol and thiopental, sodium thiosulfate, sodium nitrite and ascorbic acid. - Simultaneous administration of hydroxocobalamin and blood products through the same intravenous line is not recommended. **SPECAIL PRECAUTIONS FOR STORAGE*:** Do not store above 25°C. The reconstituted solution has to be used immediately. **SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING*:** Each vial is to be reconstituted with 100 ml of diluent (sodium chloride 9 mg/ml (0,9 %) solution for injection) using the supplied sterile transfer device. The intravenous infusion set provided in the kit must then be used. **MARKETING AUTHORISATION HOLDER:** Merck Santé s.a.s., Lyon, France. **MARKETING AUTHORISATION NUMBER:** EU/1/07/420/001.

* For more details please refer to SmPC on the EMEA website.

Merck Serono Emergency Care

MERCK SERONO

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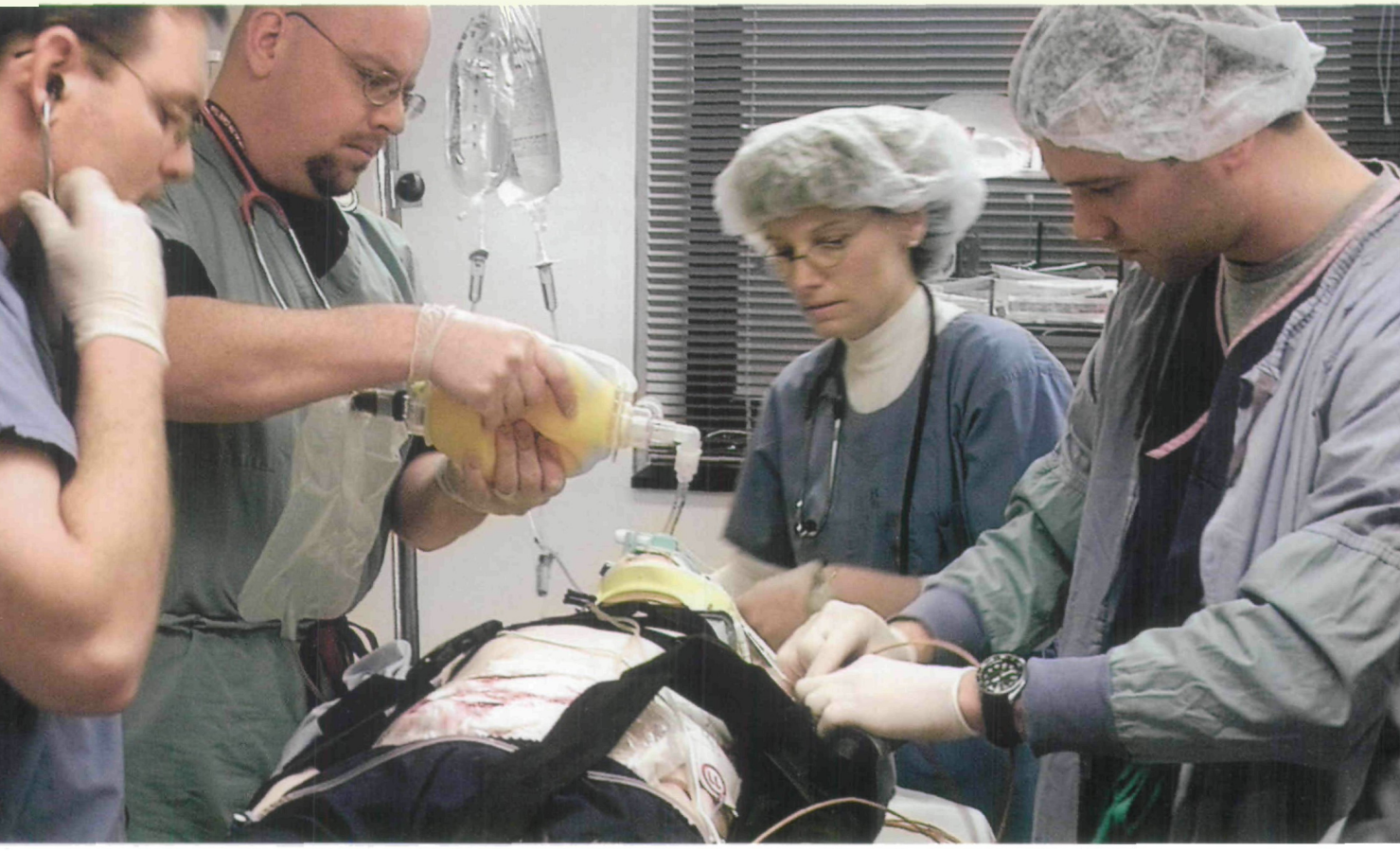
Bringing Simulation to Life



SimMan®

There is a growing awareness that health care is behind other high risk operations in its attention to ensuring basic safety and that there is a need to grasp the scale of the problem [1,2].

Use of patient simulation is considered an important part of the solution as many scenarios can be presented including uncommon but critical situations where a rapid response is needed. Errors can be allowed to occur and reach their conclusion without any risk to a patient. Team member interactions and leadership can also be explored and developed.

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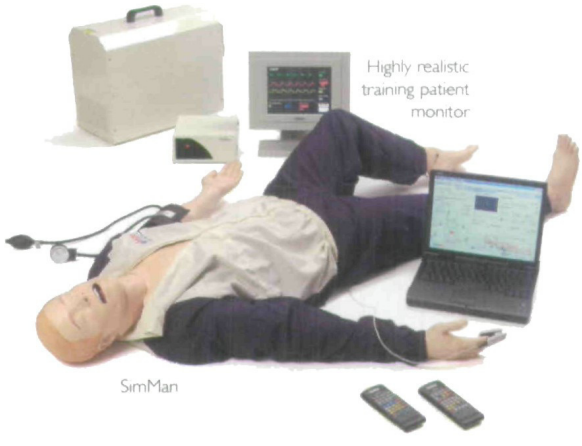

References:
1) BMJ Volume 320, 18 March 2000
2) To Err Is Human: Building a Safer Health System/Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Editors., © 2000 by the National Academy of Sciences.

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GLOBAL DISASTER MANAGEMENT TEA

Thai Tsunami Victim Identification Centre

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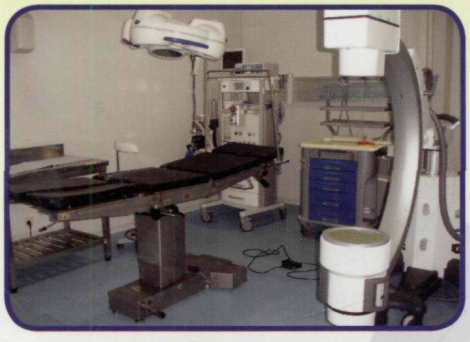
MSF Hospital, Hattian Bala, Pakistan



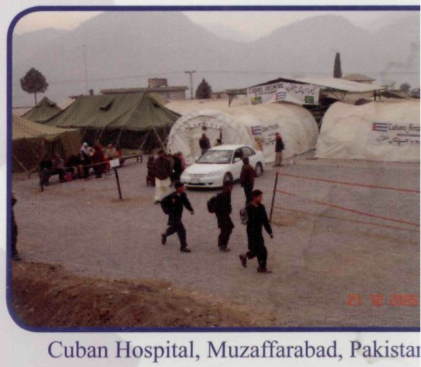
Inside OT in KATIKO Referral Hospital

Normeca AS

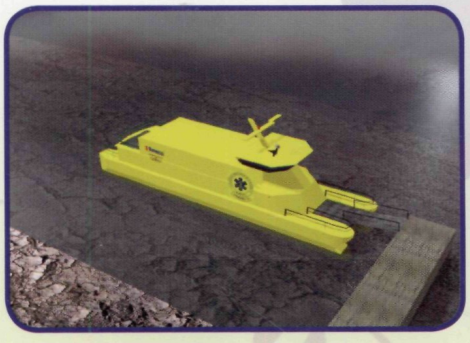
Number One
in
the world
within
partly and turn key
solutions
incl.
Transportation,
Erection,
Management,
Training,
Maintenance,
Education,
Administration,
Storage,
Out sourcing,
Medivac,
etc.

Inside MSF Hospital in Hattian Bala

All kinds of clinics or hospitals in MultiSpace



Cuban Hospital, Muzaffarabad, Pakistan



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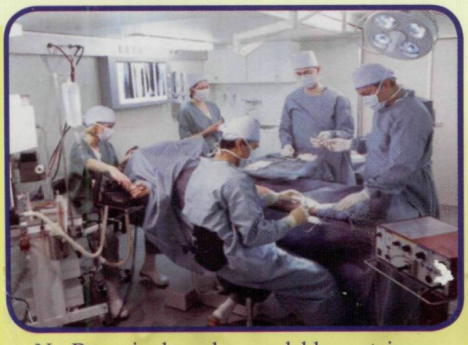
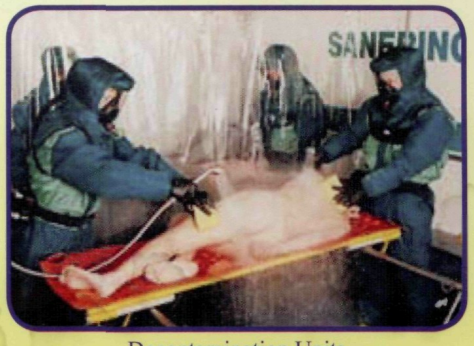


NorBase single and expandable containers



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