Dexamethasone

Section: 22. Medicines for reproductive health and perinatal care > 22.6. Other medicines administered to the mother

Codes ATC: H02AB02

Indication	Respiratory distress syndrome of the newborn, altered by maternal corticosteroid therapy Code ICD11: KB23.00
INN	Dexamethasone
Type de médicament	Chemical agent
Type de liste	Liste de base
Formulations	**Parenteral > General injections > unspecified:** 4 mg per mL (dexamethasone phosphate (as sodium))
Historique des statuts LME	Ajouté pour la première fois en 2013 (TRS 985)
Sexe	Féminin
Âge	Adolescents et adultes
Équivalence thérapeutique	La recommandation concerne ce médicament spécifique
Renseignements sur le brevet	Patents have expired in most jurisdictions Lire la suite sur les brevets.
Wikipédia	Dexamethasone
DrugBank	Dexamethasone

Résumé des preuves et recommandation du comité d'experts

An application was submitted by Dr Joy Lawn, Director of Global Evidence and Policy Saving Newborn Lives/Save the Children, London, United Kingdom and Fernando Althaea Instituto de Efectividad Clínica y Sanitaria, Buenos Aires, Argentina, for the addition of dexamethasone for the indication of accelerating lung maturation in preterm babies. Preterm birth is the leading cause of neonatal deaths and the second most common cause of under-5 mortality, as well as a leading contributor to the global burden of disease because of a significant risk of disability. Each year an estimated 15 million babies are born preterm, three-quarters of them in South Asia and sub-Saharan Africa. Over 85% are moderate or late preterm, who are likely to survive without intensive care. However, if access to basic care is limited, antenatal corticosteroids could make a considerable difference to mortality and morbidity, primarily by reducing the risk of respiratory distress syndrome (RDS). There is high-quality evidence showing that antenatal corticosteroids reduce all-cause neonatal mortality. A Cochrane review and meta-analysis of 18 trials (3956 infants) of antenatal corticosteroids found that the risk of neonatal mortality was reduced by approximately 30% (relative risk, RR: 0.69, 95% CI: 0.58–0.81) (1). The same meta-analysis found that there was reduced incidence of RDS (RR: 0.66, 95% CI: 0.59–0.73, 21 studies, 4038 infants) and cerebroventricular haemorrhage (RR: 0.54, 95% CI: 0.43–0.69, 13 studies, 2872 infants). A meta-analysis of four randomized controlled trials (672 infants) from middle-income countries found a decrease in neonatal mortality following preterm birth (RR: 0.47, 95% CI: 0.35–0.64). No studies were found from low income settings (2). Two products – dexamethasone and betamethasone – were used in the majority of trials. No differences in effects were found between the two products. A large trial that is powered to detect a difference was continuing at the time of the 19th meeting of the

Expert Committee but results were not expected until 2015 (3). The adverse effects of dexamethasone are well defined. A retrospective cohort study compared preterm babies exposed prenatally to dexamethasone to those not exposed and found no differences in verbal intelligence quotient, performance intelligence, body length, head circumference and body weight at one, three and six years (4). Dexamethasone is recommended in WHO global clinical guidelines such as Managing complications in pregnancy and childbirth: a guide for midwives and doctors (5). The National Institutes of Health (6), the American College of Obstetricians and Gynecologists (7), and the Royal College of Obstetricians and Gynaecologists (8) have recommended antenatal corticosteroid treatment for women at risk for preterm delivery before 34 weeks of gestation to reduce the morbidity and mortality associated with preterm birth. The most extensively studied regimens of corticosteroid treatment for the prevention of RDS are two doses of betamethasone 12 mg given intramuscularly 24 hours apart, or four doses of dexamethasone 6 mg given intramuscularly 12 hours apart. Evidence for other dosing regimens, such as the commonly used two doses of betamethasone 12 mg given 12 hours apart, is sparse, but it would seem reasonable to use a regimen that delivers 24 mg of either drug within a 24–48-hour period (8). Dexamethasone is generally inexpensive (< US$ 1 per four-injection course) and is widely available, making it the cheapest and most accessible means of preventing RDS and deaths due to preterm birth. Dexamethasone treatment is likely to be cost-effective in most settings, at an estimated cost per case (including the cost of syringes, needles, swabs, personnel and clinic visits) of US$ 16.25, which is around one-third the cost of betamethasone treatment. Dexamethasone was already listed on the EML in the same formulation (4 mg/ml) that is commonly used for this indication. Given the compelling evidence of effectiveness, safety and cost– effectiveness, the Expert Committee recommended the inclusion of dexamethasone in Section 29, under a new subheading of “Medicines for administered to the mother”.

1. Roberts D, Dalziel S. Antenatal corticosteroids for accelerating fetal lung maturation for women at risk of preterm birth. Cochrane Database Syst Rev. 2006;(3):CD004454. http://dx.doi. org/10.1002/14651858.CD004454.pub2 PMID:16856047 2. Mwansa-Kambafwile J, Cousens S, Hansen T, Lawn JE. Antenatal steroids in preterm labour for the prevention of neonatal deaths due to complications of preterm birth. Int J Epidemiol. 2010;39 Suppl 1:i122-33. http://dx.doi.org/10.1093/ije/dyq029 PMID:20348115 3. Brownfoot FC, Crowther CA, Middleton P. Different corticosteroids and regimens for accelerating fetal lung maturation for women at risk of preterm birth. Cochrane Database Syst Rev. 2008;(4):CD006764. http://dx.doi.org/10.1002/14651858.CD006764.pub2 PMID:18843729 4. Liu J, Feng ZC, Li J, Wang Q. Antenatal dexamethasone has no adverse effects on child physical and cognitive development: a long-term cohort follow-up investigation. J Matern Fetal Neonatal Med. 2012;25(11):2369-71. http://dx.doi.org/10.3109/14767058.2012.696162 PMID:22631044 5. World Health Organization, United Nations Population Fund, UNICEF, The World Bank. Managing complications in pregnancy and childbirth: a guide for midwives and doctors. Geneva: World Health Organization; 2007. 6. Effect of corticosteroids for fetal maturation on perinatal outcomes. NIH Consensus Statement. 1994;12(2):1-24. PMID:7728157 7. ACOG Committee on Obstetric Practice. Committee Opinion No. 475: Antenatal corticosteroid therapy for fetal maturation. Obstet Gynecol. 2011;117(2 Pt 1):422-4. http://dx.doi.org/10.1097/ AOG.0b013e31820eee00 PMID:21252775 8. Antenatal corticosteroids to reduce neonatal morbidity and mortality. London: Royal College of Obstetricians and Gynaecologists; 2010 (http://www.rcog.org.uk/files/rcog-corp/GTG%207.pdf, accessed 27 November 2013).

