Ventolin (salbutamol sulphate): Limitations on use for inhibition of premature labour

Your attention is drawn to the Singapore Health Sciences Authority’s (HSA) announcement regarding limitations on use of Ventolin (salbutamol sulphate) for inhibition of premature labour.

The HSA announces that there are important restrictions regarding the use of oral and parenteral Ventolin in the treatment of premature labour. Obstetric use of short-acting beta-agonists (SABA), including salbutamol sulphate, is associated with serious, sometimes fatal, adverse cardiovascular events in both the mother and the foetus or newborn. Oral salbutamol sulphate should not be used in the treatment of premature labour and the use of parenteral salbutamol sulphate should be limited to inhibition of premature labour between the 22nd and 37th weeks of gestation for a maximum of 48 hours and administered with close monitoring of both mother and foetus. In addition, parenteral salbutamol sulphate should not be used in women with a history of heart disease or in any conditions where prolongation of the pregnancy is hazardous to the mother and foetus.

Please refer to the HSA’s website for details:

In Hong Kong, there is one registered pharmaceutical product containing injectable salbutamol, namely Ventolin Soln for I.V Infusion 1mg/ml (HK-02796). It is a prescription-only medicine and is registered by GlaxoSmithKline Limited (GSK). It is indicated for the relief of severe bronchospasm and for the short-term management of uncomplicated premature labour. GSK has already updated the package insert to include the above safety information. So far, the Department of Health (DH) has not received any local adverse drug reaction report related to the product. The DH will keep vigilant on any safety update related to the product by other drug regulatory authorities. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under “ADR reporting”: http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office’s website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Grant NG)
for Assistant Director (Drug)