MEG Demo (Staff App) - MEG Demo - MEG Staff app: Prescribing in pregnancy

General Information on prescribing in pregnancy

Prescribing in pregnancy

Drugs should be prescribed in pregnancy only if the expected benefit to the mother is thought to be greater than the risk to the fetus, and all drugs should be avoided if possible during the first trimester.

Drugs which have been extensively used in pregnancy and appear to be usually safe should be prescribed in preference to new or untried drugs; and the smallest effective dose should be used.

Few drugs have been shown conclusively to be teratogenic in humans, but no drug is safe beyond all doubt in early pregnancy. Screening procedures are available when there is a known risk of certain defects.

Absence of information does not imply safety.

• The use of any medicine during pregnancy requires careful consideration of both risks and benefits by the treating health professional.

Any decision about taking a medicine during pregnancy should involve a health professional and the patient and should take into account:

- all available information on the medicine
- the specific circumstances

Information on the safety of specific drugs in pregnancy may be found in the manufacturer's Summary of Product Characteristics (SPC) accessible via the Health Products Regulatory Authority (HPRA) Website-<u>www.hpra.ie</u> and the eBNF available via Maternet. In the US the FDA has established five categories (A,B,C,D, and X) to indicate a drug's potential for causing teratogenicity. Table 1 below summarises the FDA pregnancy risk category of commonly used antimicrobial drugs. This should not be used as the sole source of information and more extensive information on the safety of antimicrobial drug use in pregnancy should be sought from the Medicines Information Service, Pharmacy Department where possible.

Antibiotic risk ratings in pregnancy

Table 1: FDA Risk Categories of antimicrobials in pregnancy.

Antimicrobial	FDA Category*
Antibiotics	85
Aminoglycosides:	D
Gentamicin, amikacin, tobramycin	
Beta-lactams:	
Amoxicillin Coamoxiclay Piperacillin/Tazobactam	В
	в
Cephalosporins	в
Aztreonam	C C
Imipenem/cilastatin	B
Meropenem, Ertapenem	
Chloramphenicol	C
Quinolones:	
Ciprofloxacin, Moxifloxacin, levofloxacin	c
Clindamycin	в
Colistin	C
Daptomycin	В
Fostomycin	В
Fidaxomicin	В
Fusidic acid	Potential for Neonatal Kernicterus
Linezolid	C
Macrolides:	
Erythromycin, Azithromycin	В
Clarithromycin	C C
Metronidazole	В
Nitroturantoin	В
Quinopristin-Daltoprostin	В
Ritaximin	C
Sulphonamides/trimethoprim	C
Tetracyclines: Doxycycline, tigecycline	D
Vancomycin	C
Antifungais	
Amphotericin	В
Anidulatungin	C
Caspotungin	C
Fluconazole	D (C – if 150mg single dose for vaginal candidiasis)
Itraconazole	C
Ketoconazole	С
Posaconazole	C
Voriconazole	D
Terbinatine	В
Flucytosine	C

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FDA Pregnancy Risk category definitions

FDA Pregnancy Categories*

A: Controlled studies in women fail to demonstrate a risk to the foetus in the first trimester (and there is no evidence of a risk in later trimesters), and the possibility of foetal harm appears remote.

B: Either animal-reproduction studies have not demonstrated a foetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters).

C: Either studies in animals have revealed adverse effects on the foetus (teratogenic or embryocidal or other) and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the foetus.

D: There is positive evidence of human foetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g. if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

X: Studies in animals or human beings have demonstrated foetal abnormalities or there is evidence of foetal risk based on human experience or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

References:

1. Sanford Guide to Antimicrobial Therapy 2013 43rd Edition.

2. Micromedex Drug Consult Reference: Pregnancy Risk Categories. Accesed online via www.micromedexsolutions.com , July 2014.

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