

Off label use of misoprostol

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“Misoprostol seems excellent for use in obstetrics and gynaecology”



“But its not licensed, and the drug company haven’t approved it. You will be in trouble if you use it”

Outline

1. History of misoprostol
2. Drug company attitudes
3. Licensing laws
4. Clinical negligence / risk
5. The way forward

Misoprostol: clinical use

- 1985 first licensed for gastric ulcers (Searle)
- 1987 first clandestine use for abortion
(by 1989, illegal use in Brazil common)
- 2005 WHO essential drug list
- 2005 Misoprostol goes off patent
- 2012 > 50 'misoprostols' available (many licensed for abortion, labour induction, PPH)

No license applied for cytotec

- Searle decision not to apply for it
 - Already lucrative market in gastroenterology
 - Cost
 - Bad publicity on ‘abortion drug’ (mife)
 - Concerns re birth outcomes

What is a licence?

- Protect patients from drug companies
(came out of thalidomide crisis)
- NOT to protect patients from doctors



Licensing of drugs

- Usually new expensive drugs in low risk indications

NOT FOR

- Old drugs in new indications
- Cheap / generic drugs
- High risk situations (paeds / O&G)

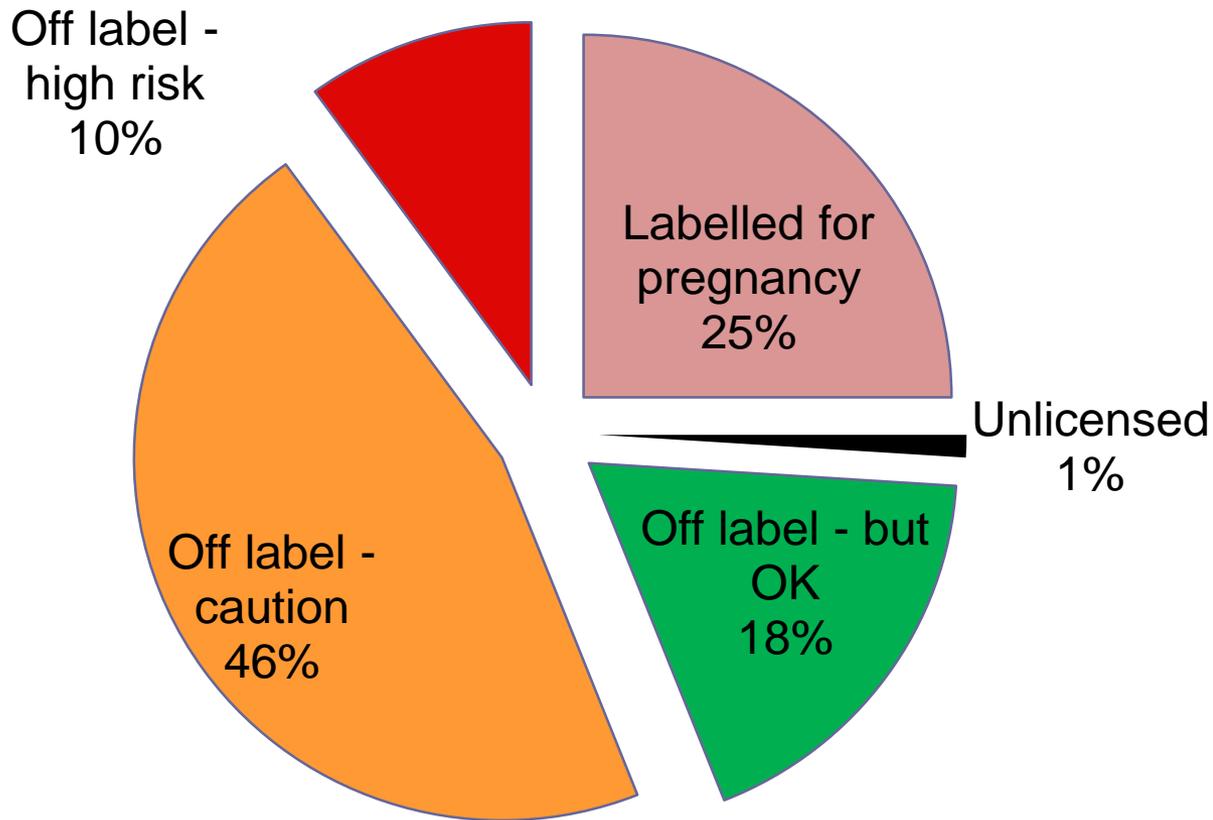
Which are licensed in the UK?

- a. Misoprostol to prevent PPH ✗ (✓)
- b. Oxytocin 10iu im to prevent PPH ✗
- c. Methotrexate for unruptured ectopic ✗
- d. Magnesium sulphate for eclampsia ✗
- e. Betamethasone for fetal lung maturation ✗

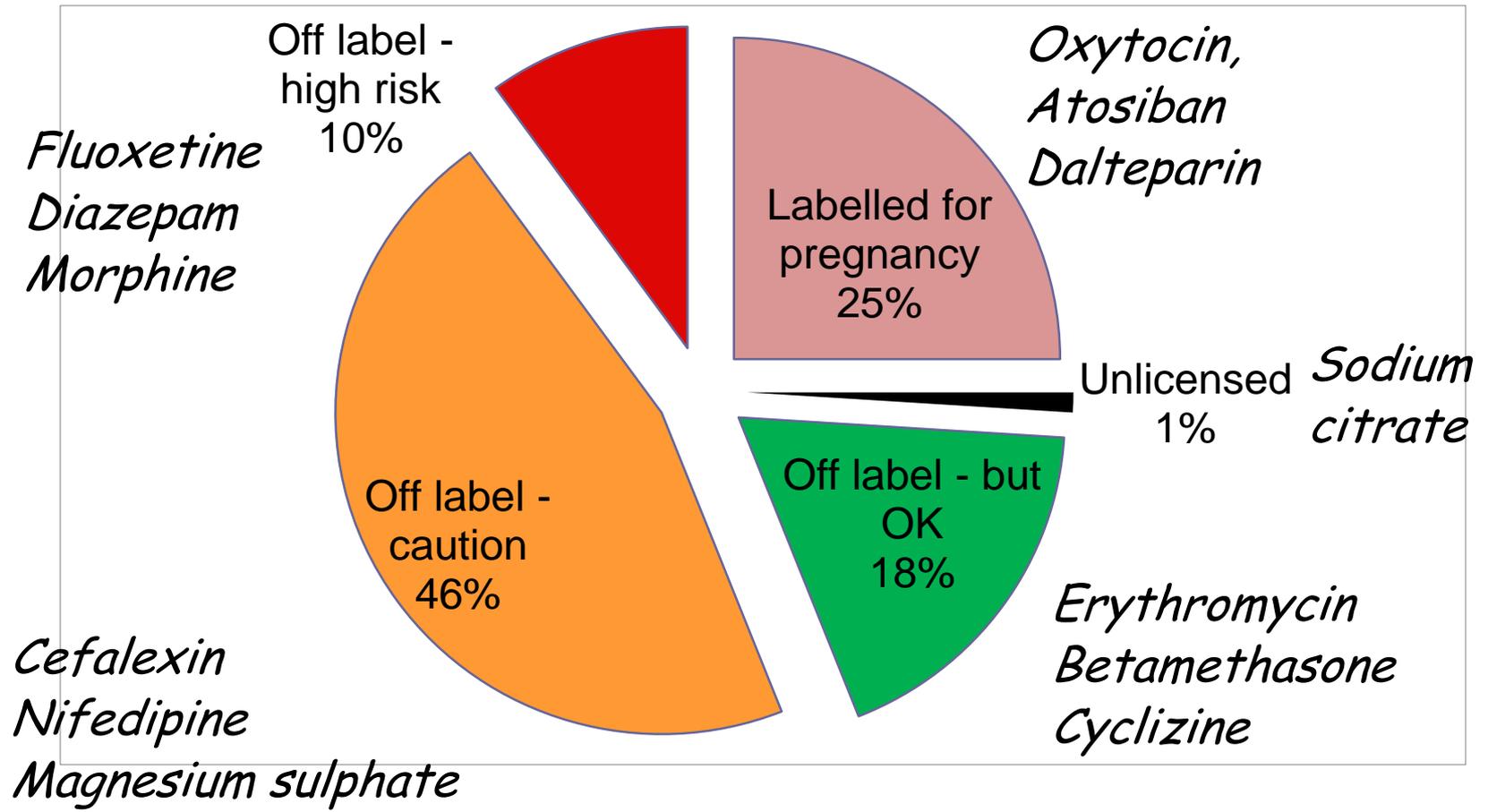
The “reassuring licence?”

- Presence of a licence generally reassuring
 - But licences get out of date
 - e.g. oxytocin for missed abortion, luteal norethisterone for menorrhagia
- Lack of a licence means little to a clinician

Antenatal prescribing at LWH



17,694 prescriptions of 235 drugs in 3 months



Will I get sued for prescribing an off-label drug?

Legal tests in UK:

Bolam test (1957)

‘what a representative group of doctors at the same level would reasonably be expected to do’

Bolitho Test (1997)

‘a judge is entitled to reject an opinion which is logically indefensible’

What would a representative group do?

1. National government guidelines
2. Local guidelines or formulary
3. WHO / FIGO / association guidelines
4. Licence

Misoprostol use for abortion

“ Yes ”

- RCOG / ACOG
- WHO
- Specialist societies
- Generic companies

“ No ”

- Pfizer

MHRA on 'off-label' prescribing

Before prescribing a medicine off-label:

- be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative
- be satisfied that there is sufficient evidence ... to show its safety and efficacy

Where current practice supports the use of a medicine outside the terms of its licence, it may not be necessary to draw attention to the licence when seeking consent.

The Way Forward

1. Ignore the lack of a drug licence
2. Ensure protection for prescribers
 - evidence-based guidelines
 - statements from RH organisations e.g. WHO, FIGO, Gynuity
3. Ensure safe use for patients
 - products with correct dose formulations and dosage instructions
 - publicity for correct dosages

www.misoprostol.org



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