

## Update on Meloxicam (*Mobicox*<sup>®</sup>) & COX-2 Selectivity

### COX-2 Selectivity/Specificity

◆ There is a lot of discussion regarding the relative COX-2 selectivity of meloxicam compared to celecoxib (*Celebrex*<sup>®</sup>) and rofecoxib (*Vioxx*<sup>®</sup>). A December 2000 *RxFiles Q&A Summary* regarding meloxicam stated that it had “relatively selective but not specific COX-2 inhibition” as discussed in a variety of literature.<sup>1,2,3,4,5</sup> Boehringer Ingelheim (Canada) Ltd. (BICL) has been detailing meloxicam as an agent with COX-2 selectivity comparable to celecoxib based on data from BICL sponsored work of Warner et al.<sup>6</sup> This research measured NSAID inhibition of COX-1 when COX-2 enzyme activity is inhibited by 80%. It found that both meloxicam and celecoxib were 5-50 fold selective for COX-2, with rofecoxib being >50 fold COX-2 selective. The interpretation of studies measuring relative COX-2 to COX-1 selectivity is subject to much debate due to differences in the various assays used. As with rofecoxib and celecoxib, meloxicam does not appear to affect platelet aggregation, a trait that supports high COX-2 selectivity.<sup>7</sup>

◆ The fight over the COX-2 market share has resulted in discussion regarding the suitability of the term “**COX-2 specific**” which has been used for both celecoxib and rofecoxib. According to a recent memorandum, the Pharmaceutical Advertising Advisory Board (PAAB) has stated that “no product has received approval for use of the term “COX-2 specific” in advertising because it is not in the product monograph of any of the three drugs” (*Mobicox*<sup>®</sup>, *Vioxx*<sup>®</sup>, and *Celebrex*<sup>®</sup>). A look at current evidence regarding actual safety data (e.g. risk of complicated GI ulcers) will be more relevant to this discussion.

### GI Tolerability and Safety

◆ Unfortunately no head-to-head clinical data is available to compare rofecoxib or celecoxib to meloxicam.

◆ Two large-scale, short-term 28day trials have assessed the GI tolerability of meloxicam (see **Table**):

◆ **MELISSA**<sup>8</sup> showed that compared to diclofenac SR 100mg/day, meloxicam 7.5mg/day caused less GI related adverse drug reactions (ADRs) (13% vs 19%; p=0.001). These ADRs included dyspepsia, nausea & vomiting, abdominal pain and diarrhea. There were 5 (0.1%) serious GI events defined as perforations, ulcers, or bleeds (PUBs) in the meloxicam group compared to 7 (0.15%) in the diclofenac group. While this showed a positive trend it was not statistically significant.

◆ **SELECT**<sup>9</sup> showed that compared to piroxicam 20mg/day, meloxicam 7.5mg/day caused less GI related ADRs (10.3% vs 15.4%; p=0.001). There were 7 (0.16%) serious GI events (e.g. PUBs) in the meloxicam group compared to 16 (0.37%) in the piroxicam group. Again the difference lacked statistical significance.

◆ The **short duration** and **low-doses** (7.5mg OD) used make it difficult to evaluate the risk for serious GI ADRs; GI ulcer risk can increase greatly with higher NSAID dosages.

◆ A meta-analysis reporting on 12 randomized meloxicam trials suggests that compared to non-COX-2 selective NSAIDs, meloxicam has fewer GI ADRs, less dyspepsia, fewer PUBs, and less frequent discontinuation due to

adverse GI events.<sup>10</sup> This data must be cautiously interpreted due to the inherent limitations of the meta-analysis, such as variability of trial outcomes, and the low dosage of meloxicam used in most trials.

◆ **Meloxicam appears to have better GI tolerance than non-selective NSAIDs. To what extent ulcers and complicated ulcers are also reduced remains to be established.**

◆ Major trials evaluating the safety of the other COX-2 selective drugs, **celecoxib** (*Celebrex*<sup>®</sup>) and **rofecoxib** (*Vioxx*<sup>®</sup>) have been published. These trials differ from the large-scale meloxicam trials as **dosages were 2-4X higher than usually recommended and trial length was longer** (see Table).

◆ The **CLASS**<sup>11</sup> study compared celecoxib to non-selective NSAIDs (ibuprofen and diclofenac). The risk of “GI ulcer complications + symptomatic ulcers” were significantly reduced; however significant reductions in complicated ulcers was reduced only for the study arm where patients on ASA were excluded.

◆ The **VIGOR**<sup>12</sup> study compared rofecoxib to naproxen and found significant reductions in complicated ulcers in rofecoxib patients. As opposed to the CLASS trial, ASA patients were excluded from the study and a small increase in risk of acute MI was seen.

◆ These trial results pose many more questions that will require further study (& more updates).

### Approximate cost per 30 day prescription in SK (includes allowable markup and dispensing fee):

- ◆ naproxen 375mg po BID (~ \$16)
- ◆ meloxicam 7.5mg po OD (~ \$32)
- ◆ celecoxib 200mg po OD (~ \$52)
- ◆ rofecoxib 12.5mg po OD (~ \$52)

<sup>1</sup> Jackson LM, Hawkey C. COX-2 Selective Nonsteroidal Anti-inflammatory Drugs. *Drugs* 2000;59(6):1207-16.

<sup>2</sup> Kaplan-Machlis B, Klostermeyer BS. The Cyclooxygenase-2 Inhibitors: Safety and Effectiveness. *Ann Pharmacother* 1999;33:979-88.

<sup>3</sup> Meloxicam and selective COX-2 inhibition: the evidence for improved gastrointestinal tolerability. *Drugs and Therapy Perspectives* 1996;8(2):1-4.

<sup>4</sup> Hawkey CJ. COX-2 Inhibitors (New Drug Classes). *Lancet* 1999;353:307-14.

<sup>5</sup> Tegeder I, Lotsch J, Krebs S, Muth-Selbach U, Brune K, Geisslinger G. Comparison of inhibitory effects of meloxicam and diclofenac on human thromboxane biosyntheses after single doses and at steady state. *Clin Pharmacol Ther* 1999;65:533-44.

<sup>6</sup> Warner TD, Giuliano F, Vojnovic I, Bukasa A, Mitchell JA, Vane JR. *Proc Natl Acad Sci USA* 1999;96:7563-8.

<sup>7</sup> Hecken A, Schwartz JI, Depre M, et al. Comparative inhibitory activity of rofecoxib, meloxicam, diclofenac, ibuprofen, and naproxen on COX-2 versus COX-1 in healthy volunteers. *J Clin Pharmacol* 2000;40:1109-20.

<sup>8</sup> Hawkey C, Kahan A, Steinbruck K, et al. Gastrointestinal tolerability of meloxicam compared to diclofenac in osteoarthritis patients. International MELISSA Study Group. *Br J Rheumatol* 1998;37:937-45.

<sup>9</sup> Dequeker J, Hawkey C, Kahan A, et al. Improvement in gastrointestinal tolerability of the selective cyclooxygenase (COX)-2 inhibitor meloxicam, compared with piroxicam: Results of the Safety and Efficacy Large-scale Evaluation of COX-inhibiting Therapies (SELECT) trial in osteoarthritis. *Br J Rheumatol* 1998;37:946-51.

<sup>10</sup> Schoenfeld P. Gastrointestinal safety profile of meloxicam: a meta-analysis and systematic review of randomized controlled trials. *Am J Med* 1999;107:48S-54S.

<sup>11</sup> Langman MJ, Jensen DM, Watson DJ, et al. Adverse upper gastrointestinal effects of celecoxib compared with NSAIDs (CLASS). *JAMA* 1999;282:1929-33.

<sup>12</sup> Bombardier C, Laine L, Reicin A, et al. Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis (VIGOR). *NEJM* 2000;343:1520-1528. <sup>{11,12}</sup> Note: additional study results (CLASS/VIGOR) - [www.fda.gov/ohrms/doctet](http://www.fda.gov/ohrms/doctet)

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**MELOXICAM (Mobicox®)**

Study	Drug & Dose	Duration	# pts	Any GI adverse event – 28days (dyspepsia, etc.)	Perforations or Bleeds - 28 days	Perforations, Ulcers, or Bleeds (PUBs) - 28days	Any event causing DC	Comments
<b>MELISSA</b> <sup>8</sup> (n=9323) Mean age=61.5	Meloxicam 7.5mg OD Diclofenac 100mg SR OD	28 days OA	4635 4688	13% 19% (p<0.001)	0 4 not significant	0.1% 0.15% not significant	7.2% 9% (p=0.0014) (due to ADR or ↓efficacy)	<ul style="list-style-type: none"> <li>♦higher hospitalization rate in diclofenac group</li> <li>♦diclofenac group had more pts age &gt;65 &amp; pts with hx of PUBs</li> <li>♦more pts in meloxicam group discontinued due to lack of efficacy but less due to adverse reactions.</li> </ul>
<b>SELECT</b> <sup>9</sup> (n=8656) Mean age=61.5	Meloxicam 7.5mg OD Piroxicam 20mg OD	28 days OA	4320 4336	10.3% 15.4% (p<0.001)	0 4 not significant	0.16% 0.37% not significant	6.13% 7.24% (p=0.06) NS	<ul style="list-style-type: none"> <li>♦piroxicam group: more &gt;65yo; but less with a hx of PUBs</li> <li>♦withdrawals due to GI adverse events less with meloxicam vs piroxicam (3.79% vs 5.26%) p&lt;0.01%</li> </ul>

**What we know:** ♦meloxicam was better tolerated and caused fewer withdrawals due to GI adverse events than non-selective NSAIDs.

**What we don't know:** ♦whether meloxicam significantly reduces the risk of complicated and symptomatic ulcers compared to non-selective NSAIDs can not be determined from these trials; differences shown in these studies were not statistically significant and the **low-dose (1/2 usual maximum) and short duration (28days)** of the studies makes interpretation difficult.

**Meloxicam long-term data:** Has been used outside of North America since 1996; >30million prescriptions in > 90 countries); One abstract reports clinically significant GI ADRs/pt-year=0.3 & 0.6 (for 7.5 & 15mg/d dose).

**CELECOXIB (Celebrex®) & ROFECOXIB (Vioxx®)** Detailed study results for CLASS & VIGOR obtained from submission to FDA arthritis advisory committee Feb01 - <http://www.fda.gov/ohrms/docket>

Study	Drug & Dose	Duration	# pts	Any GI adverse events	GI ulcer complications / 100 pt-yrs	GI ulcer complications + symptomatic ulcers / 100 pt-yrs	Any event causing DC	Comments
<b>CLASS</b> <sup>11</sup> (n=7968)  Mean age=60 (~12% >75) (range 18-90)	Celecoxib 400mg BID Ibuprofen 800mg TID Diclofenac 75mg BID	≤6mo; ave 4.2mo OA or RA 72%	3987 1985 1996	45.6% 46.2% NS 55.0% (p<0.05)	0.76 1.45 (p=0.09) not significant	2.08 3.54 (p=0.02) NNT=68.5	22.4% 23.0% NS 26.5%	<ul style="list-style-type: none"> <li>♦supratherapeutic doses used to definitively test safety</li> <li>♦'ulcer complications' defined as: upper GI bleeding, perforation, or gastric obstruction</li> <li>♦dose of celecoxib 2X usual max daily dose</li> <li>♦only 4573 completed full 6 month trial; high drop out rate</li> <li>♦ &gt; withdrawal rate due to GI ADR in diclofenac group (16.6% vs 12.2% for celecoxib) may have underestimated its GI risk</li> <li>♦differences in GI ulcers/complications were found for celecoxib versus ibuprofen (2.08 vs 4.31/100 pt-yrs; p=0.005) but not celecoxib vs diclofenac (possibly due to &gt; withdrawal rate)</li> <li>♦pts at ↑ risk for GI events also had ↑ withdrawal rates</li> <li>♦fewer celecoxib pts had GI blood loss, GI intolerance</li> <li>♦no difference in CV events (but ASA allowed in study)</li> <li>♦celecoxib arm had more pts &gt; 65yo &amp; hx of upper GI bleeds</li> <li>♦rash with high-dose celecoxib (6.2%); appears to be dose-dependent ↑ from previous data; (sulfa allergy pts excluded)</li> </ul>
	Subgroup: as above but excluding patients on ASA ≤325mg/d	ASA appeared to be an independent cause of ulcers in celecoxib pts, but not for NSAIDs (RR =4.5).		0.44 1.27 (p=0.04) NNT=120	1.40 2.91 (p=0.02) NNT=66			
	Subgroup: as above but including patients on ASA ≤325mg/d	~22% of each treatment arm had concurrent ASA		2.01 2.12 (p=0.92) not significant	4.7 6.0 (p=0.49)			
<b>VIGOR</b> <sup>12</sup> (n=8076)  Mean age 58; (only ~5% >75) (range 34-89)	Rofecoxib 50mg OD Naproxen 500mg BID	≤13mo; mean 8mo  RA	4047 4029	32.6% 36%	0.59 1.37 (p=0.005) NNT=128	2.08 4.49 (p=0.001) NNT=41.5	15.9% 15.8% NS	<ul style="list-style-type: none"> <li>♦dose of rofecoxib 2X usual max daily dose</li> <li>♦acute MI &gt; in rofecoxib than naproxen (0.5% vs 0.1%)</li> <li>♦DC due to hypertension &gt; in rofecoxib (0.7% vs 0.1%); HTN &amp; edema appear to be dose dependent (previous data)</li> <li>♦DC due to GI ADR lower in rofecoxib (RR = 0.73; p&lt;0.001)</li> <li>♦similar incidence of rash (rofecoxib vs naproxen 3.5% vs 3%)</li> <li>♦better GI safety but some adverse outcomes related to non-GI events; ASA pts excluded; ♦rofecoxib arm had less pts age &gt;65</li> </ul>

**What we know:** ♦rofecoxib reduced the risk of complicated &/or symptomatic ulcers but increased the risk of acute MI compared to the non-selective NSAID, naproxen.

♦celecoxib significantly reduced the risk of complicated &/or symptomatic ulcers compared to ibuprofen

♦risk of serious ulcer complications in patients on celecoxib and low-dose ASA was not significantly different from those on non-selective NSAIDs and ASA.

**What we don't know:** ♦whether risk of serious GI toxicity in patients on rofecoxib and ASA would be reduced compared to patients on non-selective NSAIDs and ASA.

♦whether the safety profile would be significantly improved in patients on a usually recommended or lowest effective dose as opposed to supratherapeutic doses from trials.

♦whether COX-2 selective agents are significantly safer in high-risk patients (e.g. the very elderly ≥75yrs or patients with previous hx of ulcers).

♦how the selective COX-2 agents compare to each other in terms of overall safety or efficacy. (No head-to-head trials; different trial designs.)

**Celecoxib long-term data:** Study 024: ulcer complication rate of 0.23% (≤2 years exposure); postmarketing surveillance incidence of ulcer complications <0.02%; 30 fatal GI events in 1999; acute renal failure 0.0039%.

**Rofecoxib long-term data:** postmarketing surveillance - 59 complicated PUBs in 1999 (but only approved May/1999); complicated upper GI events = 0.014 per 100 pt-yrs;

**Background rate of ulcers:** estimated to be approximately 0.1 to 0.4 events per patient years (varying as function of patient age); general ulcer rate for NSAIDs is thought to be ~2-4% per year; risk ↑'s with ↑d dose;

acute renal failure secondary to NSAIDs = 15-20 per 100,000 pt-yrs; NSAIDs account for 16,500 deaths/year in the USA

**Of interest, MUCOSA study:** misoprostol (200mcg po qid) ↓d the rate of serious complicated upper GI events from 0.95% to 0.56% for NSAID users with RA over 6 months (ARR =0.4%; NNT=250)

DC=discontinuation; OA=osteoarthritis; RA=rheumatoid arthritis; yo=years old; NS=not (statistically) significant; GI=gastrointestinal; ADR=adverse drug reaction; CV =cardiovascular; pts =patients; hx =history.



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