

**new**  
**idarac**<sup>®</sup>  
floctafenine 200 mg

fills an analgesic need  
separating potency from  
side effects

### Prescribing information

**idarac**

floctafenine 200 mg tablets

#### THERAPEUTIC CLASSIFICATION

Analgesic

#### ACTION

IDARAC (floctafenine) is an anthranilic acid derivative which has analgesic and anti-inflammatory properties. Floctafenine has been shown to inhibit *in vitro* biosynthesis of prostaglandins PGE<sub>2</sub> and PGF<sub>2α</sub>. Gastro-intestinal bleeding, determined by daily fecal blood loss, was shown in one clinical trial to be approximately 1.2 ml after 1600 mg/day of floctafenine compared to 10.4 ml after 2400 mg/day of acetylsalicylic acid.

In normal volunteers, IDARAC was well absorbed after oral administration and peak plasma levels were attained 1-2 hours after administration and declined in a biphasic manner, with an initial (α phase) half-life of approximately 1 hour and 1 later (β phase) half-life of approximately 8 hours. Floctafenine and its metabolites do not accumulate following oral administration of multiple doses.

After oral and intravenous administration of <sup>14</sup>C labelled IDARAC, urinary excretion accounted for 40% and fecal and biliary excretion accounted for 60% of the recovered radioactivity. The main urinary metabolites are floctafeninic acid and its conjugate with minimal amounts of free floctafenine.

#### INDICATIONS

IDARAC (floctafenine) is indicated for short-term use in acute pain of mild and moderate severity.

#### CONTRAINDICATIONS

IDARAC (floctafenine) is contraindicated in patients with peptic ulcer or any other active inflammatory disease of the gastro-intestinal tract, and in patients who have demonstrated a hypersensitivity to the drug.

#### WARNINGS

**Use in Pregnancy:** The use of IDARAC (floctafenine) in women of childbearing potential requires that the likely benefit of the drug be weighed against the possible risk to the mother and fetus. Use of the drug in women who are nursing is not recommended.

**Use in Children:** The safety and efficacy of IDARAC in children have not been established and therefore is not recommended. The safety and efficacy of long-term use of IDARAC have not been established.

#### PRECAUTIONS

IDARAC (floctafenine) should be used with caution in patients with impaired renal function. In clinical trials with IDARAC, dysuria without apparent changes in renal function, was reported. It has not been established whether dysuria is related to dose and/or duration of drug administration.

Patients taking anticoagulant medication may be given IDARAC with caution. Alterations in prothrombin time have been observed only in clinical trials where the administration of IDARAC was extended beyond two weeks.

IDARAC should be used with caution in patients with a history of peptic ulcer or other gastro-intestinal lesions.

#### ADVERSE REACTIONS

The most commonly occurring side effects reported during IDARAC (floctafenine) therapy were:

**Central Nervous System:** Drowsiness, dizziness, headache, insomnia, nervousness, irritability.

**Gastro-intestinal System:** Nausea, diarrhea, abdominal pain or discomfort, heartburn, constipation, abnormal liver function, gastro-intestinal bleeding.

**Urogenital System:** Dysuria, burning micturation, polyuria, strong smelling urine, urethritis and cystitis.

**Allergic-type Reactions:** Maculopapular skin rash, pruritis, urticaria, redness and itching of the face and neck.

#### SYMPTOMS AND TREATMENT OF OVERDOSE

No cases of overdose have been reported with IDARAC (floctafenine). In a case of overdose, standard procedures to evacuate gastric contents, maintain urinary output and provide general supportive care should be employed.

#### DOSE AND ADMINISTRATION

The usual adult dose of IDARAC (floctafenine) is 1 to 2 tablets (200 to 400 mg), 3 to 4 times per day as required. The maximum recommended daily dose is 1200 mg. IDARAC is recommended for short-term management of acute pain.

The tablets should be taken with a glass of water.

IDARAC is not recommended for use in children.

#### AVAILABILITY

Each tablet of IDARAC contains 200 mg of floctafenine. Tablets are biconvex, cylindrical, yellowish-white, scored on one side with D57 above the breakline and the Roussel logo on the reverse side.

IDARAC is available in bottles of 100 tablets. Store at room temperature, protected from light.

IDARAC is a Schedule F (prescription) drug.

**References:** 1. Lomas, D.M., Gay, J., Midha, R.N., and Postlethwaite, D.L.: A Double-Blind Comparative Clinical Trial of Floctafenine and Four Other Analgesics Conducted in General Practice. *Journal of International Medical Research*. Vol. 4, No. 3, 179-182, 1976. 2. Vickers, M.D., Akbar, F.A.: Floctafenine (IDARAC), a new analgesic: a comparison with placebo in chronic pain. *Journal of International Medical Research*. Vol. 3, 32-37, 1975.

## Campylobacter infections

To the editor: Campylobacter infections are now well recognized. However, one feature of infection with campylobacter enteritis that is not well emphasized is the presence of an inflammatory cellular exudate in the stools. We report a case in which this was a predominant feature.

### Case report

A 22-year-old steelworker and his brother had eaten chicken at a local Chinese restaurant. The next day fever and chills developed in the steelworker and were followed by diffuse cramp-like abdominal pain associated with the passage of six loose bloody stools. Two days later he was admitted to hospital.

The results of physical examination were normal, apart from a temperature of 39.5°C. The hemoglobin concentration was 15.3 g/dl and the leukocyte count 17.9 × 10<sup>9</sup>/l. The patient was treated with intravenously administered saline and acetaminophen. By the next day he had improved and the bloody diarrhea was less frequent.

Gram staining of stool samples showed large numbers of pus cells. *Campylobacter jejuni* was isolated on Skirrow's medium. No ova or parasites were found, and blood cultures gave negative results.

The patient made a full recovery without antibiotic therapy.

Although he lived in a rooming house where the cooking facilities were shared, he was the only person so affected.

### Discussion

In his original description of campylobacter enteritis Skirrow<sup>1</sup> stated that he found a polymorphonuclear exudate in only 18 of 57 samples; however, he did not state how many samples were examined by smear. Several subsequent accounts have described abdominal pain and diarrhea as the two outstanding features of campylobacter enteritis.<sup>2,3</sup> The presence of pus cells in a significant proportion of cases implies an invasive component to the pathogenesis of campylobacter enteritis; however, the mechanism of the diarrhea has yet to be fully elucidated. The diagnosis of campy-

lobacter infection has to be entertained in any patient with an acute diarrheal illness associated with pus cells.

We thank the bacteriology laboratory of Toronto East General and Orthopaedic Hospital Inc. for its technical assistance.

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### References

1. SKIRROW MB: Campylobacter enteritis: a "new" disease. *Br Med J* 2: 9, 1977
2. Campylobacter enteritis (E). *Lancet* 2: 135, 1978
3. KARMALI MA, FLEMING PC: Campylobacter enteritis. *Can Med Assoc J* 120: 1525, 1979

## The use of propranolol in treating tardive dyskinesia

To the editor: Beta-adrenergic blocking agents are being used more and more for a variety of conditions, including ischemic heart disease, hypertension and cardiac dysrhythmias. They have also been found useful in the treatment of essential tremor, as the following case illustrates.

### Case report

In 1977 a 55-year-old woman with neurotic depression and excessive drinking was admitted to a psychiatric facility. She was treated with clomipramine hydrochloride tablets. At the time of discharge clomipramine was discontinued because of the development of tardive dyskinesia — specifically, mouth movements. Psychiatric consultations continued for over a year. Unfortunately, the patient was unable to carry on with her daily activities without such medications as tricyclic antidepressants or a phenothiazine derivative. The tardive dyskinesia persisted and became a great problem for her.

In October 1979 I thought it might be worth trying propranolol to modify the annoying mouth movements. Initially, I prescribed

PAAB

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10 mg to be taken four times a day; I soon increased the dose to 40 mg to be taken twice a day. Over approximately 6 weeks the mouth movements decreased; propranolol was continued at 80 mg/d.

I last saw the patient 1 week before the time of writing, when she stated that she had run out of the propranolol and had not bothered to renew the prescription. She found that the mouth movements returned quite rapidly; therefore, she immediately began taking propranolol again, 40 mg twice a day.

#### Comment

I hope this report stimulates interest in and investigation into the use of propranolol or other  $\beta$ -adrenergic blocking agents in the treatment of tardive dyskinesia.

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#### Legal abortions among teenagers, 1974-78

*To the editor:* It was difficult to read the article by S. Wadhra and C. Nair (*Can Med Assoc J* 122: 1386, 1980) without being overwhelmed by the sheer numbers of abortions currently being performed world-wide. Certainly the death of one person affects us more deeply than the deaths of many, mainly because we cannot fully appreciate the significance or the impact of a major disaster. Nevertheless, there has to be some revulsion, no matter how we try to suppress it, at the thought of 30 to 55 million abortions being performed annually throughout the world. If this is too much to comprehend realistically, then it is no less alarming to look closer to home and perceive that 62 290 abortions were performed in 1978 in Canada alone, which constitutes a rate of 11.3/1000 women aged 15 to 44 years. This rate, however, is misleading; the true enormity of the problem is more accurately depicted if we look at the abortion problem in terms of the percentage of pregnancies terminated.

Wadhra and Nair give all the

relevant figures only for 1976, when there were 360 000 live births and 54 478 abortions in Canada. This signifies a mortality of approximately 15% for all fetuses, excluding those miscarried. The law states that an abortion should be performed only if in the opinion of a therapeutic abortion committee the continuation of the pregnancy would or would be likely to endanger the mother's life or health.<sup>1</sup> It is very difficult to believe that as many as 15% of pregnancies are so dangerous. Certainly if we accept the ludicrous definition of health as proposed by the World Health Organization,<sup>2</sup> then many pregnancies are dangerous to the health; indeed, we might be excused for believing that pregnancy is a pathologic condition and that we could conceivably terminate all pregnancies with the blessing of the World Health Organization.

The situation is untenable; we can no longer be considered true professionals, but rather mere technicians responding to the demands of the public.

Whether or not we regard the fetus as human (if we do, we calmly committed 62 000 murders in Canada in 1978) we must at least acknowledge that the fetus is potentially one of our human brethren. In that case, any society that has such little regard for its young is degenerate. Have the floodgates of irrationality opened too wide or is there still time for us to restore the founding principle of our profession — a deep reverence for life?

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*To the editor:* I disagree with Wadhra and Nair's simplistic conclusion that improved education on birth control will decrease the horrendous number of abortions among teenagers in Canada. They have aptly isolated the statistics for teenagers and have done an excellent survey of abortions; however, they have neither medical degrees nor the medical expertise to inform physicians as to how abortions among

teenagers may be curtailed. It would have been more fitting for Dr. Christopher Tietze, who guided their work, to make the conclusions and draw any criticism or opprobrium that he could have defended with his expertise on abortion and population control.

The conclusion that education on birth control should be improved indicates that perhaps the teenagers had abortions because of poor birth control or none at all. Yet, Wadhra and Nair glibly quote the Criminal Law Amendment Act, which categorically states that an abortion can only be performed if the life or health of the mother is in danger.<sup>1</sup> Therefore, there is a deep suspicion that these teenagers had abortions because they did not want the pregnancy to continue. This indeed is improved birth control; it is virtually abortion on demand.

Wadhra and Nair state that the proportion of therapeutic abortions in teenagers with previous induced abortions increased slightly in terms of percentages of the total number of abortions in all teenagers. In fact, the actual number nearly doubled between 1974 and 1978. Therefore, in a supposedly well-informed and motivated group there is a serious ignorance of birth control, which cannot be rectified no matter how persuasive the educative technique.

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#### References

1. *Criminal Code, Revised Statutes of Canada, 1970*, Dept of Justice, Ottawa, chap C-34, sec 251, 1970
2. World Health Organization: Text of the Constitution of the World Health Organization. *Off Rec WHO* no 2: 100, 1948

#### "Diagnosis of Diseases of the Chest" [correction]

Dr. Anthony S. Rebeck has informed us that, in his review of this book (*Can Med Assoc J* 123: 399, 1980), his address was incorrectly given as McMaster University, Hamilton. Dr. Rebeck is, in fact, at the Toronto General Hospital. We apologize for this oversight. — Ed.