

Smoking prevalence and associated risk factors in Canadian adults

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Objective: To describe the prevalence and patterns of smoking among Canadian adults, the relation of smoking to other cardiovascular disease risk factors and the awareness of the causes of heart disease.

Design: Population-based cross-sectional surveys.

Setting: Nine Canadian provinces, from 1986 to 1990.

Participants: A probability sample of 26 293 men and women aged 18 to 74 was selected from the health insurance registries in each province. Of these, 20 585 completed a questionnaire on smoking habits during a home interview.

Main results: Approximately 29% of the Canadian population 18 years of age and over were regular cigarette smokers, and over 13% of regular smokers smoked more than 25 cigarettes per day. The proportion of women who had never smoked was higher (37%) than men (24%), except for young women aged 18 to 24. For all participants, there was a lower prevalence of high blood pressure and overweight among smokers than non-smokers. The prevalence of sedentary lifestyle, diabetes and elevated blood cholesterol was positively associated with smoking. The proportion of subjects who identified smoking as a cause of heart disease was higher among smokers, and over 90% believe that heart disease is preventable.

Conclusion: Because smoking is positively associated with other cardiovascular risk factors, multifactorial and comprehensive approaches are needed in the implementation of cardiovascular disease prevention programs. Knowledge regarding the heart health hazards of smoking is high even among smokers. Motivational approaches that go beyond health risk messages are needed in cessation programs.

The numerous deleterious health effects of smoking are well documented. Mortality rates in Canada for male and female smokers are 70 and 30% higher, respectively, than those for non-smokers, largely due to the increase in risk of dying from lung cancer, bronchitis, emphysema and cardiovascular disease (CVD).^{1,2,3} An estimated 35 000 deaths were attributed to tobacco use in Canada in 1985. This accounts for almost 30% of all deaths among those 35 years of age and older.⁴ Many other conditions are also associated with smoking: cervical, pancreatic, kidney and oral cancers,⁵ and osteoporosis.⁶ Furthermore, pregnant women who smoke have more stillbirths and spontaneous abor-

tions and their babies have lower birthweights and are more likely to die soon after birth.⁷

In both men and women, mortality rates for cerebrovascular disease are higher for smokers than for non-smokers.⁸ There is an increased risk among women that suggests a synergistic effect between cigarette smoking and the use of oral contraceptives.⁹ This risk increases after age 35.¹⁰

A review of the health benefits of smoking cessation indicates that people who quit smoking before age 50 reduce their risk of death by 50% over a period of 15 years.¹¹ Smoking cessation reduces the risk of a number of cancers, including lung, oral cavity, esophagus, pancreatic, bladder and cervix, by

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as much as 50%. The risk of coronary heart disease (CHD) declines by about 50% after 1 year of smoking abstinence.¹¹

Since 1965, Health and Welfare Canada has monitored the smoking behaviour of Canadians through supplements of the Canada Labour Force Surveys.^{12,13} The percentage of regular cigarette smokers has been declining in Canada for the last 15 years. Other one-time national surveys have also collected data on smoking habits: the Canada Health Survey (1981),¹⁴ the General Social Survey (1985),¹⁵ the Canada Health Promotion Survey (1985)¹⁶ and the Campbell Survey on Well-Being (1988).¹⁷

This paper reports the prevalence and patterns of smoking habits among Canadian adults and the relation of smoking to other cardiovascular disease (CVD) risk factors and to knowledge and awareness of the causes and consequences of heart disease.

Methods

Non-institutionalized men and women, aged 18 to 74, in nine Canadian provinces (Nova Scotia, New Brunswick, Prince Edward Island, Newfoundland, Quebec, Manitoba, Saskatchewan, Alberta, British Columbia) participated in surveys conducted between 1986 and 1990. Details of the survey methods are described in the paper on survey methods and data analysis (pages 1969–1974). In brief, a probability sample of 26 293 people was selected from the health insurance registration files of each province. Trained survey nurses administered a standard questionnaire and recorded two blood pressure measurements during a home visit. Participants subsequently visited a survey clinic within 2 weeks. Two blood pressure measurements were again recorded, anthropometric measurements were performed and a blood specimen was taken for plasma lipid determination.

The questions regarding smoking habits in the provincial heart health surveys constitute a subset of those used by the Labour Force Survey.^{12,13} The target population of the Labour Force Survey includes people 15 years of age and over; in this study the population was 18 to 74 years of age. Comparison to the surveys performed earlier should be interpreted accordingly. The methods used to measure parameters other than smoking habits are described in the paper on survey methods and data analysis (pages 1969–1974).

Data from each province were compiled into a common database, which forms the basis of this report. All percentage estimates are weighted to reflect the sampling design and the degree of non-response. Age-standardized estimates are based on the age-sex distribution of the 1986 population of Canada. Cell sizes are greater than 20 unless indicat-

ed. Overall there was a 78% response rate for the interview segment of the survey.

Results

Prevalence of smoking

Approximately 33% of participants were cigarette smokers. Regular cigarette smokers constituted 29% of the population, occasional cigarette smokers 4% and pipe or cigar smokers 1% (Table 1). Overall, there was little difference in rate of cigarette smoking between men (34%) and women (32%). Men and women under age 45 were equally likely to be regular smokers, whereas among those over 45, men were more likely than women to be regular cigarette smokers.

Non-smokers (ex-smokers and those who had never smoked) constituted 65% of the population. Ex-smokers represented 35% of the population, those who had never smoked 30%. Because of the historical differences in smoking trends of men and women, the percentage of ex-smokers was higher for men (39%) than women (31%). For both men and women, the percentage of ex-smokers increased steadily with age. Thirty-seven percent of women and 24% of men had never smoked. The percentage of men who had never smoked decreased with age, but the reverse was true for women over age 35: 48% of women and only 12% of men aged 65 and over had never smoked.

About 20% of regular smokers smoked 1 to 10 cigarettes per day, 67% smoked 11 to 25 per day and 13% smoked over 25 cigarettes per day (Table 2). In general, men (17%) were more likely than women (9%) to smoke over 25 cigarettes a day. Among men, the greatest average daily consumption occurred in the 45–65 age group and among women in the 35–55 age group. Overall average daily consumption for men was 21.1 cigarettes and for women 18.6 cigarettes.

Smoking and other risk factors

The age-standardized prevalence of other CVD risk factors was compared between smokers and non-smokers and between smokers with different levels of consumption (Table 3). Regardless of smoking status, men consistently had a higher prevalence than women of all CVD risk factors except diabetes.

For both sexes, there was a lower prevalence of high blood pressure among smokers than non-smokers. For men, the prevalence of high blood pressure was not increased in heavy smokers (more than 25 cigarettes per day). However, there was a marked increase in the prevalence of high blood

pressure in women who smoked more than 25 cigarettes per day.

For both men and women, the percentage of smokers with a sedentary lifestyle was much higher than that of non-smokers, and among smokers this percentage markedly increased with the number of cigarettes smoked per day.

The prevalence of self-reported diabetes was slightly lower among non-smokers than among

smokers. For men, there was little change in the prevalence of self-reported diabetes in relation to the number of cigarettes smoked; for women the prevalence of diabetes was considerably higher in those who smoked over 25 cigarettes per day.

Using a body mass index (BMI) equal to or greater than either 25 or 27 to define overweight, smokers were less likely to be overweight than non-smokers. Examination of age-specific rates (not

Table 1: Prevalence of smoking by sex and age

Sex; age, yr*	No. of subjects	% of subjects				
		Nonsmokers		Cigarette smokers		
		Never smoked	Former smokers	Regular	Occasional	Pipe or cigar smokers*
Men						
18-24	1701	41	21	33	4	1
25-34	3433	31	27	35	5	2
35-44	1401	23	37	32	4	3
45-54	912	15	48	31	2	5
55-64	903	13	60	22	3	2
65-74	1764	12	65	16	4	3
All	10114	24	39	30	4	2
Women						
18-24	1753	37	24	32	7	0
25-34	3667	31	30	34	5	0
35-44	1443	33	30	33	4	0
45-54	1002	38	33	26	4	0
55-64	906	44	35	18	3	0
65-74	1700	48	36	12	3	0
All	10471	37	31	28	4	0
Total	20585	30	35	29	4	1

*Excludes cigarette smokers who also smoke a pipe or cigars.

Table 2: Distribution of regular cigarette smokers by number of cigarettes per day, sex and age

Sex; age, yr*	No. of Subjects	Number of cigarettes per day; % of smokers			
		1-10	11-25	> 25	Mean no. of cigarettes per day
Men					
18-24	559	21	76	4	16.7
25-34	1210	16	72	12	20.1
35-44	422	18	61	20	21.5
45-54	272	10	62	28	25.7
55-64	244	16	54	30	24.5
65-74	323	20	70	10	19.6
All	3030	17	67	17	21.1
Women					
18-24	589	29	67	4	16.0
25-34	1259	23	70	7	18.2
35-44	434	18	71	12	20.5
45-54	275	19	65	16	20.8
55-64	176	25	69	5	17.5
65-74	237	38	53	9	15.8
All	2970	23	68	9	18.6
Total	6000	20	67	13	19.9

shown) revealed that this applies at all ages in men; however, for women aged 18 to 24, the prevalence of overweight (BMI ≥ 25) was greater among smokers (27%) than among non-smokers (21%). For both male and female smokers, the percentage who are overweight increased with the number of cigarettes smoked per day.

Elevated total cholesterol (over 5.2 mmol/L) was more prevalent among smokers than non-smokers. Prevalence increased with number of cigarettes smoked per day for women.

Smokers and non-smokers were divided into two groups, those with a BMI of 27 or more and

those with a BMI of less than 27, to discriminate between the effects of smoking and obesity on plasma lipids (Table 4). Male smokers had a slightly higher prevalence of elevated low density lipoprotein (LDL) cholesterol and triglycerides than non-smokers. The prevalence of elevated total cholesterol differed little between smokers and non-smokers among those with a BMI of less than 27. However, the prevalence of elevated total cholesterol is higher among smokers than non-smokers among those with a BMI of 27 or more. The prevalence of depressed high density lipoprotein (HDL) cholesterol levels was greater among smokers than non-smokers, espe-

Table 3: Age-standardized prevalence of risk factors for cardiovascular disease among nonsmokers and regular cigarette smokers by sex and level of smoking*

Risk factors†	Nonsmokers, %	No. of cigarettes per day; smokers, %			
		Total	1-10	11-25	> 25
Men					
High blood pressure	17 (7080)	14 (3034)	20 (474)	12 (2096)	18 (460)
High cholesterol level	45 (6001)	47 (2345)	49 (375)	46 (1604)	48 (362)
Body mass index ≥ 25	56 (6313)	50 (2481)	50 (394)	51 (1702)	53 (381)
≥ 27	35 (6313)	32 (2481)	33 (394)	31 (1702)	39 (381)
Sedentary	34 (7068)	46 (3033)	45 (474)	46 (2095)	51 (460)
Diabetes	4 (6442)	5 (2652)	5 (414)	6 (1837)	3 (397)
Women					
High blood pressure	13 (7501)	10 (2971)	10 (706)	9 (2008)	22 (256)
High cholesterol level	42 (6234)	44 (2336)	42 (556)	43 (1568)	48 (211)
Body mass index ≥ 25	39 (6589)	35 (2472)	33 (594)	35 (1657)	43 (220)
≥ 27	28 (6589)	23 (2472)	18 (594)	24 (1657)	28 (220)
Sedentary	33 (7492)	41 (2970)	38 (705)	40 (2008)	59 (256)
Diabetes	5 (6799)	6 (2581)	5 (639)	6 (1722)	14 (219)

*Sample sizes are in parentheses.

†High blood pressure = diastolic pressure ≥ 90 mm Hg or on treatment (pharmacological or non-pharmacological, [weight control, or salt restriction]); high cholesterol level = total plasma cholesterol level ≥ 5.2 mmol/L; sedentary = leisure-time physical activity less than once a week during the last month; diabetes = self-reported.

Table 4: Age-standardized prevalence of unfavourable lipid profile by smoking status and body mass index (BMI) by sex*

Lipid profile	Smokers, %		Nonsmokers, %	
	BMI < 27	BMI ≥ 27	BMI < 27	BMI ≥ 27
Men				
Total cholesterol level ≥ 5.2 mmol/L	42 (1555)	58 (772)	44 (3549)	51 (2408)
LDL-cholesterol level ≥ 3.4 mmol/L	39 (1547)	47 (717)	37 (3504)	43 (2308)
HDL-cholesterol level < 0.9 mmol/L	11 (1545)	28 (765)	8 (3532)	18 (2391)
Triglyceride level ≥ 2.3 mmol/L	13 (1555)	40 (771)	12 (3550)	30 (2408)
Women				
Total cholesterol level ≥ 5.2 mmol/L	42 (1700)	53 (609)	39 (4183)	48 (1975)
LDL-cholesterol level ≥ 3.4 mmol/L	32 (1684)	42 (594)	29 (4147)	39 (1941)
HDL-cholesterol level < 0.9 mmol/L	4 (1690)	15 (606)	1 (4165)	5 (1966)
Triglyceride level ≥ 2.3 mmol/L	11 (1700)	24 (609)	7 (4182)	16 (1975)

*Sample sizes are in parentheses.

cially those who were overweight (BMI \geq 27). The pattern among women was comparable to that seen in men, although there was an even more striking difference in the prevalence of depressed HDL-cholesterol levels between smokers and non-smokers.

Among women in the 18–24 age group, the prevalence of oral contraceptive use was slightly higher in smokers than in non-smokers (Table 5). For the other age groups, there was no apparent difference in the use of oral contraceptives between smokers and non-smokers. Between the ages of 35 and 44, contraceptive use was low (2%) among both smokers and non-smokers.

The percentage of people who identified smoking as a cause of heart disease was higher among smokers than non-smokers at all ages (Table 6). This percentage was lower in women over 55 years than in the younger age groups (not shown), and women reported the knowledge more frequently than men. A high proportion of both smokers and non-smokers reported the belief that heart disease is preventable (averaging over 90%). People under 55 years old (not shown) reported this belief slightly more often.

Discussion

Data from the Labour Force Survey^{12,13} suggest that there has been an impressive decline in the percentage of adults who smoke; prevalence rates

dropped from 50% in 1966 to 34% in 1986. According to the results of this study, the decline appears to be continuing but at a slower rate. Our data represent only nine provinces and a 5-year period (1986 to 1990), thus, comparisons with the Labour Force Survey should be interpreted cautiously.

Tobacco sales also are decreasing at a substantial rate,¹⁸ which is further evidence of the decrease in smoking.¹⁹ More men than women have stopped smoking and, in younger age groups, smoking has increased in women. As a result, the difference in smoking prevalence between the sexes has diminished. However, men are still heavier smokers (more than 25 cigarettes per day) than women. Statistics on lung cancer¹⁹ reflect the reported increase in smoking among women over the past 15 years; young women have thus become a major target of anti-smoking programs.

As smoking restrictions at work and throughout the community make it increasingly difficult for people to smoke, the number of smokers in Canada will continue to decline. However, those who smoke, particularly in the older age groups, may need tailored and individual approaches to help them quit.

If we look at the reasons for starting or continuing to smoke, we find numerous determinants that vary with age and sex.²⁰ To intervene successfully requires a multidimensional approach such as that demonstrated in the Community Intervention Trial for Smoking Cessation (COMMIT)²¹ in which approximately 40 intervention activities are being applied over 4 years to reduce the prevalence of heavy smokers in 11 communities in North America.

The association of smoking with CVD has been well documented.^{22–27} We also know that smoking in the presence of other risk factors for CHD has a synergistic effect on CVD mortality.²⁸

The association of physical activity and risk for CHD has been observed in men²⁹ but has not been consistently identified in women.³⁰ A sedentary lifestyle is often linked to a cluster of other negative health habits, including smoking.³¹ Our study dem-

Table 5: Prevalence of oral contraceptive use among smokers and nonsmokers by age*

Age; yr	Smokers	Nonsmokers
18–24	48 (589)	44 (1154)
25–34	23 (1257)	21 (2387)
35–44	2 (433)	2 (1008)
45–54	0 (274)	1 (723)
55–64	0 (176)	0 (730)
65–74	0 (235)	0 (1451)
Total	16 (2964)	11 (7453)

*Sample sizes are in parentheses.

Table 6: Age-standardized distribution* of people reporting knowledge of smoking as a cause of heart disease and perceiving heart disease as being preventable, by smoking status and by sex

Variable	Men, %		Women, %	
	Smokers	Nonsmokers	Smokers	Nonsmokers
Know smoking causes heart disease	57 (3034)	42 (7077)	59 (2969)	41 (7497)
Perceive heart disease being preventable	90 (3033)	94 (7075)	89 (2971)	92 (7497)

*Age-standardized to the total Canadian population in 1986.

onstrates a notably higher prevalence of sedentary lifestyle among smokers.

There is evidence that people with multiple risk factors should begin health promotion actions that will ensure early success,³² as success in one area leads to attention to other lifestyle areas. For smokers who are concerned about weight gain when they stop smoking, it may be useful to recommend increasing physical activity to prevent their efforts to stop smoking from being undermined. Exercise and weight reduction are seen as methods to promote other healthy behaviours including the prevention or cessation of smoking.³³

The observation that high blood pressure was less common among smokers than non-smokers may reflect the lower prevalence of obesity among smokers. However, the reverse is true for heavy smokers. Hypertensive people who smoke have up to five times the risk for CVD of hypertensive people who do not smoke; however they can lower their coronary risk if they stop smoking.^{23,34} Considering the documented prevalence of hypertension among heavy smokers (18% to 22%) and the associated synergistic risk for CVD, smoking cessation should be considered as an adjunct to therapy for hypertensive people who smoke.

A significant increase in risk for CHD among diabetic patients who smoke has been demonstrated in some studies,³⁵ although the strength of this relationship has not always been clear.³⁶ Diabetes is also one of the few conditions where the risk for CVD is similar for men and women.³⁴ Diabetic patients should be advised to refrain from smoking,³⁷ and their concerns about weight control should be taken into account to help their cessation efforts.

The general tendency for smokers in this study to weigh less than non-smokers has been observed by others.³³ It may be that for smokers, smoking serves as a method of weight control. The 1986 Health Promotion Survey¹⁶ noted that many more smokers (30%) than non-smokers believed that smoking helped them remain slim. Fear of gaining weight may undermine smoking cessation efforts in some individuals. This pattern is reversed, however, for women in the 18–34 age group.

One mechanism through which cigarette smoking increases the risk of CVD appears to be its effect on serum lipids.³⁸ The finding in this survey that smokers experience a higher prevalence than non-smokers of elevated total cholesterol, LDL-cholesterol and triglycerides and reduced HDL-cholesterol is consistent with other major studies.^{39–41} The dose-response relation between level of smoking and the prevalence of unfavourable lipid profile has been reported by others.^{39,42} People with both these risk factors experience a greater than additive risk of CVD.²⁵ They should, therefore, be targets for inter-

ventions to reduce or remove both risk factors.

A number of studies have indicated that oral contraceptive use and cigarette smoking are independent risk factors for CHD in women. There is substantial evidence for synergism between smoking and oral contraceptive use as well as other risk factors.⁴³ Women who use oral contraceptives and who smoke are 8 to 10 times more likely to suffer myocardial infarction than those who neither use oral contraceptives nor smoke.^{43–45} There is evidence that both cigarette smoking and progestins in oral contraceptives depress HDL-cholesterol.^{46,47} Moreover, numerous studies have shown an association between cigarette smoking and cerebrovascular. The use of both cigarettes and oral contraceptives increases the risk for subarachnoid hemorrhage in women aged 35 or older.⁴⁸

The fact that about one in four female smokers in the 25–34 age group also uses contraceptives is a reason for concern and should be the object of public education programs. The low prevalence of oral contraceptive use among smokers and non-smokers after age 35 is noteworthy. Physician counselling on alternative methods of contraception for this age group seems to have been in part successful.

Health-influencing behaviour is determined by multiple factors that involve personal variables (such as knowledge, belief, attitudes), environmental factors (psychological, social, cultural) and complex interactions of people with their environment.^{49,50} Since the earliest studies of health behaviour, there has been an understanding that what people know about their personal risk and what they believe they can do to lower that risk are important determinants of behaviour.⁵¹ In this survey, over 50% of smokers knew that smoking is a cause of heart disease; this knowledge was more frequent among smokers than among non-smokers and the younger age groups.

There are several implications of these findings. It appears that smokers are aware of educational messages regarding the risks of smoking. This is consistent with the communication theory that the personal relevance of information is a determinant of attention to the information⁵² and points to the continuing need to find motivational approaches that go beyond health risk messages.⁵³ Second, smokers over the age of 55 have not been hearing the message. It appears that further efforts are needed to promote awareness of smoking as a cause of heart disease, particularly among individuals over 55.

Our findings regarding the preventability of heart disease are consistent with other studies that show that non-smokers tend to use more preventive practices.⁵⁴ It appears that the message of preventability has been heard and adopted by many people in Canada, but those over 55 do not express this belief as often as younger adults. In fact, the CHD preven-

tion message has been promoted in schools only since the early 1970s.

Conclusion

It is encouraging to find that the overall proportion of smokers is continuing to decline albeit less rapidly. Smokers, especially heavy smokers, have a high prevalence of other risk factors, such as obesity, sedentary lifestyle and unfavourable lipid profile, that places them at an increased risk of CVD. This points to the need for multifactorial and comprehensive approaches in the implementation of CVD prevention programs.

Further intervention could focus on health care professionals to address cessation as part of routine clinical preventive medicine by motivating and supporting people in smoking cessation. As weight gain associated with smoking cessation is a barrier to long-term elimination of smoking, physicians should provide information on weight control and smoking cessation at the same time. The Canadian Task Force on the Periodic Health Examination⁵⁵ and the US Preventive Services Task Force⁵⁶ have strongly recommended medical efforts to provide repeated smoking cessation messages from multiple sources over an extended period because of the demonstrated efficacy of such an approach.

Knowledge regarding the heart health hazards of smoking was high even among smokers. This draws attention to the need for motivational approaches that go beyond health risk messages. These results should be useful in planning further public education programs and in reaching smokers more effectively.

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CYTOTEC BRIEF PRESCRIBING INFORMATION

Therapeutic Classification Cytoprotective Agent

INDICATION:

CYTOTEC (misoprostol) is indicated in the treatment and prevention of NSAID-induced gastric ulcers (defined as ≥ 0.3 cm in diameter) and in the treatment of duodenal ulcers.

CONTRAINDICATIONS:

Known sensitivity to prostaglandins, prostaglandin analogues, or excipients (micro-crystalline and hydroxypropyl methylcellulose, sodium starch and hydrogenated castor oil).

Contraindicated in pregnancy.

Women should be advised not to become pregnant while taking CYTOTEC. If pregnancy is suspected, use of the product should be discontinued and the pregnancy followed very closely (weekly) for the next four weeks.

WARNINGS:

Women of childbearing potential should employ adequate contraception (i.e. oral or intrauterine devices) while receiving CYTOTEC. (See CONTRAINDICATIONS.)

Nursing Mothers: It is unlikely that CYTOTEC is excreted in human milk since it is rapidly metabolized throughout the body. However, it is not known if the active metabolite (misoprostol acid) is excreted in human milk. Therefore, CYTOTEC should not be administered to nursing mothers because the potential excretion of misoprostol acid could cause significant diarrhea in nursing infants.

Pediatric Use: Safety and effectiveness in patients below the age of 18 have not been established.

PRECAUTIONS:

Selection of Patients: Before treatment is undertaken, a positive diagnosis of duodenal ulcer or NSAID-induced gastric ulcer should be made. In addition, the general health of the patient should be considered. Misoprostol is rapidly metabolized by most body tissues to inactive metabolites. Nevertheless, caution should be exercised when patients have impairment of renal or hepatic function. Experience to date with such patients is limited.

Diarrhea: Rare instances of profound diarrhea leading to severe dehydration have been reported. Patients with an underlying condition such as irritable bowel disease, or those in whom dehydration were it to occur, would be dangerous, should be monitored carefully if CYTOTEC is prescribed.

ADVERSE REACTIONS:

Gastrointestinal: In subjects receiving CYTOTEC (misoprostol) 400 or 800 mcg daily in clinical trials, the most frequent gastrointestinal adverse events were diarrhea, abdominal pain and flatulence. The average incidences of these events were 11.4%, 6.8% and 2.9%, respectively. In clinical trials using a dosage regimen of 400 mcg bid, the incidence of diarrhea was 12.6%. The events were usually transient and mild to moderate in severity.

Diarrhea, when it occurred, usually developed early in the course of therapy, was self-limiting and required discontinuation of CYTOTEC in less than 2% of the patients. The incidence of diarrhea can be

minimized by adjusting the dose of CYTOTEC, by administering after food and by avoiding coadministration of CYTOTEC with magnesium-containing antacids.

Gynecological: Women who received CYTOTEC during clinical trials reported the following gynecological disorders: spotting (0.7%), cramps (0.6%), hypermenorrhea (0.5%), menstrual disorder (0.3%) and dysmenorrhea (0.1%).

Elderly: There were no significant difference in the safety profile of CYTOTEC in approximately 500 ulcer patients who were 65 years of age or older compared with younger patients.

Incidence greater than 1%: In clinical trials, the following adverse reactions were reported by more than 1% of the subjects receiving CYTOTEC and may be casually related to the drug: nausea (3.2%), headache (2.4%), dyspepsia (2%), vomiting (1.3%) and constipation (1.1%). However, there were no clinically significant differences between the incidences of these events for CYTOTEC and placebo.

DOSAGE AND ADMINISTRATION:

Treatment and Prevention of NSAID-Induced Gastric Ulcers: The recommended adult oral dosage of CYTOTEC for the prevention and treatment of NSAID-induced gastric ulcer is 400 to 800 mcg a day in divided doses. NSAIDs should be taken according to the schedule prescribed by the physician. When appropriate CYTOTEC and NSAIDs are to be taken simultaneously, CYTOTEC should be taken after food.

Duodenal Ulcer: The recommended adult oral dosage of CYTOTEC (misoprostol) for duodenal ulcer is 800mcg per day for 4 weeks in two or four equally divided doses (i.e. 200 mcg qid or 400 mcg bid). The last dose should be taken at bedtime. Antacids (aluminum based) may be used as needed for relief of pain. Treatment should be continued for a total of 4 weeks unless healing in less time has been documented by endoscopic examination. In the small number of patients who may not have fully healed after 4 weeks, therapy with CYTOTEC may be continued for a further 4 weeks.

AVAILABILITY:

CYTOTEC 200 mcg tablets are white to off-white — scored, hexagonal with SEARLE 1461 engraved on one side.

CYTOTEC 100 mcg tablets are white to off-white, round tablets with SEARLE engraved on one side and CYTOTEC on the other.

Store below 30°C (86°F).

Pharmacist: Dispense with Patient Insert.

Only Cytotec Protects.

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