Pregnancy

Pregnancy Category C

Safety in pregnant women has not been established. There are no adequate and well controlled studies of fenofibrate in pregnant women. Fenofibrate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In female rats given oral dietary doses of 15, 75, and 300 mg/kg/day of fenofibrate from 15 days prior to mating through weaning, maternal toxicity was observed at 0.3 times the MRHD, based on body surface area comparisons; mg/m^2.

In pregnant rats given oral dietary doses of 14, 127, and 361 mg/kg/day from gestation day 6-15 during the period of organogenesis, adverse developmental findings were not observed at 14 mg/kg/day (less than 1 times the MRHD, based on body surface area comparisons; mg/m^2). At higher multiples of human doses evidence of maternal toxicity was observed.

In pregnant rabbits given oral gavage doses of 15, 150, and 300 mg/kg/day from gestation day 6-18 during the period of organogenesis and allowed to deliver, aborted litters were observed at 150 mg/kg/day (10 times the MRHD, based on body surface area comparisons: mg/m^2). No developmental findings were observed at 15 mg/kg/day (at less than 1 times the MRHD, based on body surface area comparisons; mg/m^2).

In pregnant rats given oral dietary doses of 15, 75, and 300 mg/kg/day from gestation day 15 through lactation day 21 (weaning), maternal toxicity was observed at less than 1 times the MRHD, based on body surface area comparisons; mg/m^2.

Nursing Mothers

It is not known whether fenofibrate is excreted into milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from fenofibrate, a decision should be made whether to discontinue nursing or administration of fenofibrate taking into account the importance of the drug to the lactating woman.

Pediatric Use

Safety and efficacy in pediatric patients have not been established.

Geriatric Use

Fenofibric acid is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Fenofibric acid exposure is not influenced by age. However, elderly patients have a higher incidence of renal impairment, such that dose selection for the elderly should be made on the basis of renal function. Elderly patients with normal renal function should require no dose modifications.

ADVERSE REACTIONS

Adverse events reported by 2% or more of patients treated with fenofibrate during the double-blind, placebo-controlled trials, regardless of causality, are listed in the table below. Adverse events led to discontinuation of treatment in 5.0% of patients treated with fenofibrate and in 3.0% treated with placebo. Increases in liver function tests were the most frequent events, causing discontinuation of fenofibrate treatment in 1.6% of patients in double-blind trials.

BODY SYSTEM	Fenofibrate*	Placebo
Adverse Event	**(N=439)**	**(N=365)**
BODY AS A WHOLE		
Abdominal Pain	4.6%	4.4%
Back Pain	3.4%	2.5%
Headache	3.2%	2.7%
Asthenia	2.1%	3.0%
Flu Syndrome	2.1%	2.7%
DIGESTIVE		
Liver Function Tests Abnormal	7.5%**	1.4%
Diarrhea	2.3%	4.1%
Nausea	2.3%	1.9%
Constipation	2.1%	1.4%
METABOLIC AND NUTRITIONAL DISORDERS		
SGPT Increased	3.0%	1.6%
Creatine Phosphokinase Increased	3.0%	1.4%
SGOT Increased	3.4% **	0.5%
RESPIRATORY		
Respiratory Disorder	6.2%	5.5%
Rhinitis	2.3%	1.1%

* Dosage equivalent to 145 mg TRICOR.
** Significantly different from Placebo.

Additional adverse events reported during post-marketing surveillance or by three or more patients in placebo-controlled trials or reported in other controlled or open trials, regardless of causality are listed below.

Body as a Whole

Accidental injury, allergic reaction, chest pain, cyst, fever, hernia, infection, malaise and pain (unspecified).

Cardiovascular System

Angina pectoris, arrhythmia, atrial fibrillation, cardiovascular disorder, coronary artery disorder, electrocardiogram abnormal, extrasystoles, hypertension, hypotension, migraine, myocardial infarct, palpitation, peripheral vascular disorder, phlebitis, tachycardia, varicose vein, vascular disorder, vasodilatation, venous thromboembolic events (deep vein thrombosis, pulmonary embolus) and ventricular extrasystoles.

Digestive System

Anorexia, cholecystitis, cholelithiasis, colitis, diarrhea, duodenal ulcer, dyspepsia, eructation, esophagitis, flatulence, gastritis, gastroenteritis, gastrointestinal disorder, increased appetite, jaundice, liver fatty deposit, nausea, pancreatitis, peptic ulcer, rectal disorder, rectal hemorrhage, tooth disorder and vomiting.

Endocrine System

Diabetes mellitus.

Hemic and Lymphatic System

Anemia, ecchymosis, eosinophilia, leukopenia, lymphadenopathy, and thrombocytopenia.

Laboratory Investigations

Alkaline phosphatase increased, bilirubin increased, blood urea nitrogen increased, serum creatinine increased, gamma glutamyl transpeptidase increased, lactate dehydrogenase increased, SGOT and SGPT increased.

Metabolic and Nutritional Disorders

Edema, gout, hyperuricemia, hypoglycemia, peripheral edema, weight gain, and weight loss.

Musculoskeletal System

Arthralgia, arthritis, arthrosis, bursitis, joint disorder, leg cramps, myalgia, myasthenia, myositis, rhabdomyolysis and tenosynovitis.

Nervous System

Anxiety or nervousness, depression, dizziness, dry mouth, hypertonia, insomnia, libido decreased, neuralgia, paresthesia, somnolence and vertigo.

Respiratory System

Allergic pulmonary alveolitis, asthma, bronchitis, cough increased, dyspnea, laryngitis, pharyngitis, pneumonia and sinusitis.

Skin and Appendages

Acne, alopecia, contact dermatitis, eczema, fungal dermatitis, herpes simplex, herpes zoster, maculopapular rash, nail disorder, photosensitivity reaction, pruritus, rash, sweating, skin disorder, skin ulcer and urticaria.

Special Senses

Abnormal vision, amblyopia, cataract specified, conjunctivitis, ear pain, eye disorder, otitis media and refraction disorder.

Urogenital System

Abnormal kidney function, cystitis, dysuria, gynecomastia, prostatic disorder, unintended pregnancy, urinary frequency, urolithiasis and vaginal moniliasis.

OVERDOSAGE

There is no specific treatment for overdose with TRICOR. General supportive care of the patient is indicated, including monitoring of vital signs and observation of clinical status, should an overdose occur. If indicated, elimination of unabsorbed drug should be achieved by emesis or gastric lavage; usual precautions should be observed to maintain the airway. Because fenofibrate is highly bound to plasma proteins, hemodialysis should not be considered.

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by Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill Co. Cork, Ireland. or Laboratories Fournier SA, Rue de Pres Potets, 21121 Fontaine-les-Dijon, France.

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McCain Opposes Health Insurance Mandate

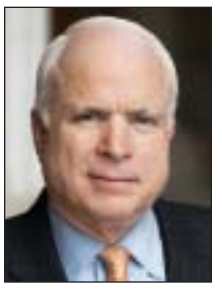
BY JOYCE FRIEDEN
Publication Editor

For Sen. John McCain (R-Ariz.), having health insurance is desirable but not mandatory.

"I don't think there should be a mandate for every American to have health insurance," the Republican presidential hopeful said at a forum on health care policy sponsored by Families USA and the Federation of American Hospitals. "I think one of our goals should be that every American own their own home, but I'm not going to mandate that. … I feel the same way about health care. If it's affordable and available, then it seems to me it's a matter of choice amongst Americans," he said.

Election 2008

As Sen. McCain sees it, health insurance is something many people decide they don't want. "The 47 million Americans that are without health insurance today, a very large portion of them are healthy young Americans who simply choose not to" sign up for it, he said at the forum, which was underwritten by the California Endowment and the Ewing Marion Kauffman Foundation. He added, however, that some people with chronic illnesses and other preexisting conditions do have problems accessing insurance, "and we have to make special provisions for them, including additional trust funds for Medicaid payments [for people] who need this kind of coverage."



'We should be paying … the doctor a certain set amount of money … related to overall care and results.'

SEN. McCAIN

Instead of mandating that people have health insurance, Sen. McCain, who is serving his fourth term in Congress, said his priority as president would be to rein in health care costs. "I'm not going to force Americans to do it; I don't think that's the role of government," he said. "But if we can bring down costs, as I believe we can . . . I'm absolutely convinced more and more people will take advantage of [health insurance]. The panacea isn't all just health care costs, but unless you address health care costs, you're never going to solve the other aspects of the health care crisis."

One way to control costs at the federal level is to not pay for medical errors involving Medicare patients, Sen. McCain said in an interview after the forum. "Right now we pay for every single procedure—the MRI, the CT scan, the transfusion, whatever it is. [Instead], we should be paying the provider and the doctor a certain set amount of money directly related to overall care and results. That way we remove the incentives now in place for overmedicating, overtaxing, and overindulging in unnecessary procedures. I also think it rewards good performance by the providers."

To expand access to health insurance, Sen. McCain is proposing a refundable tax credit of $2,500 per individual and $5,000 per family to help the uninsured buy health insurance policies. To pay for the tax credits—which would cost the government an estimated $3.5 trillion over 10 years—he proposes abolishing the tax deduction that employees currently take when they pay premiums on their employer-sponsored health plans. He would, however, leave intact the deduction employers currently take on their portion of the premiums as an incentive for employers to continue offering coverage.

"The important thing about the … refundable tax credit for employees is for them to go out and make choices," Sen. McCain said during the forum. "When it's their money and their decision, I think they make much wiser decisions than when it's provided by somebody else." And because the tax credit is refundable, low-income Americans who currently pay no taxes will receive a check for the amount of the credit, he noted.

When a reporter pointed out that the average cost of a family health insurance policy is more than $12,000 per year—far higher than the amount of the proposed family tax credit—Sen. McCain said the credit still would be beneficial. "One thing it does is if someone has a gold-plated health insurance policy, they'll start to pay taxes [on those premiums] and it may make them make different decisions about the extent and coverage of their health insurance plan," he said. "Another thing it does that I think is very important is that for low-income people who have no health insurance today, at least now they've got $2,500, or $5,000 in the case of a family, to go out and at least start beginning to have [it]."

Sen. McCain admitted that the tax credit plan "is not a perfect solution, and if not for the price tag involved, I'd make it even higher. But according to the Congressional Budget Office, by shifting the employee tax aspect of it, you save $3.5 trillion over a 10-year period, and I think that would have some beneficial effect at reducing the overall health care cost burden that we're laying on future generations." The senator said he did not have an estimate of how many uninsured people would be able to buy health insurance coverage because of the tax credit.

Sen. McCain said he does not support outlawing the "cherry-picking" that some health plans do to make certain they insure mostly healthy people. Outlawing cherry-picking "would be mandating what the free enterprise system does and that would be obviously something that I would not approve of." Instead, he favored broadening the high-risk pools that states use to provide coverage for some of their uninsured residents. ■