CLINICAL

Flu Pneumonia Rare. Mild in Children

Pneumonia was found in 14% of 936 children aged younger than 16 years with influenza, reported Dr. Elina Lahti of Turku (Finland) University Hospital and her colleagues. Nearly half (47%) of the children with both illnesses showed no specific clinical symptoms of pneumonia, and the impact of the influenza virus on the cause of pneumonia remains uncertain (Pediatr. Infect. Dis. J. 2006;25:160-4). The researchers reviewed the chest radiographs of children treated as both inpatients and outpatients in a university hospital from CAPSULES

1980 to 2003, including 743 cases of influenza A and 193 cases of influenza B. Pneumonia was found in 111 (15%) of children with influenza A and in 23 children (12%) with influenza B. There were no significant differences in laboratory or radiologic findings between the influenza A and B groups. Overall, 89% of the children with influenza and pneumonia had white blood cell counts below $15.0 \times 10^9/L$ and 55% had C-reactive protein concentrations at normal levels or slightly increased (to less than 20 mg/L). About half of the chest radiographs showed alveolar infiltrates, which suggests viral pneumonia, the researchers noted. Almost all of the children recovered without severe adverse events, although four children required ventilator care and one 12-year-old girl with congenital muscular dystrophy died due to severe pneumonia. The findings suggest that influenza pneumonia usually is benign in children and that influenza does not significantly increase the overall burden of pneumonia in previously healthy children, Dr. Lahti and her colleagues said. However, the disease burden was greater among young childrennearly two-thirds of the children in the study were aged younger than 3 years and 75% of these children were hospitalized for their illnesses.

Climate Change Shortens RSV Season

Global warming could be curtailing the respiratory syncytial virus season in England and Wales, according to a study by Dr. Gavin C. Donaldson of University College London. The seasons associated with both respiratory syncytial virus (RSV) isolation rates in laboratories and with RSV-related emergency department admission rates in England and Wales were significantly shorter—3.1 weeks and 2.5 weeks, respectively—during 1981-2004 for laboratory RSV and 1990-2004 for patients admitted to the emergency department with bronchiolitis, compared with rates in previous years (Clin. Infect. Dis. 2006;42:677-9). Dr. Donaldson reviewed the annual mean daily temperatures recorded at four locations in order to calculate the average temperatures for central England during the study periods. Overall, the average temperature increased from 9.2° C in 1981 to 10.5° C in 2004. The start of the RSV season was defined as the first week in the year in which the number of viral isolations and hospital admissions topped an established threshold, and the end of the season was the first week of the year in which the numbers fell below that threshold. The threshold was set at 60% of each year's average weekly number of isolations and hospital admissions. The findings were essentially similar if the threshold was set at 50% or 70%, although the relationship between hospital admission and temperature was not statistically significant when the threshold was set at 50%. Despite these findings, data on the association between RSV and temperature remain contradictory.

Strep Changes Cut Rheumatic Fever

Nonrheumatogenic types of group A streptococcus may be replacing rheumatogenic types in cases of acute streptococcal pharyngitis in children, said Dr. Stanford T. Shulman of Northwestern University and his colleagues. This change could be contributing to the decline of acute rheumatic fever among children in the United States, based on a comparison of data on M-type isolates from children in Chicago during 1961-1968 with data from children from Chicago and nationwide during 2000-2004 (CID 2006;42:441-7). Several rheumatic types of group A streptococcus—3, 5, 6, 14, 18, 19, and 29—were present in nearly 50% of 468 pharyngeal isolates from the 1961-1968 period, but comprised only 11% of 450 isolates from the Chicago area and 18% of 3,969 isolates nationwide during the 2000-2004 period. In contrast, the proportion of several nonrheumatogenic types—2, 4, 22, and 28—increased significantly between the study periods, from about 5% to nearly 28% of isolates, both in Chicago and nationwide. Rheumatic types 14, 18, 19, and 29 essentially vanished during the years between the two study periods. The other most significant decreases occurred in rheumatic types 3, 5, and 6, which comprised 35% of the Chicago isolates during the first study period, when acute rheumatic fever was still prevalent, but only 10% of Chicago isolates during the second study period, when acute rheumatic fever had become rare.

-Heidi Splete

Pages 22a-22ft>

Brief Summary of Prescribing Information (Nos. 1541, 1543, 1544, 3046, 7309, 7311) 03-5366-R24-Brf. Rev. July, 2004

 $\textbf{PREVACID}^{\circledR} \ (\textbf{lansoprazole}) \ \textbf{Delayed-Release} \ \textbf{Capsules}$

PREVACID® (lansoprazole) For Delayed-Release Oral Suspension

PREVACID® SoluTabTM (lansoprazole) Delayed-Release Orally

ntegrating Tablets

Delayed-Release Capsules, PREVACID SoluTab Delayed-Release Orally ng Tablets and PREVACID For Delayed-Release Oral Suspension are indicated

for:

Short-Term Treatment (4 weeks) of Active Duodenal Ulcer

H, pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence
Triple Therapy: PREVACID/amoxicillin/clarithromycin
Dual Therapy: PREVACID/amoxicillin/with a resistance of the r

Sont-Term Treatment (up to 8 weeks) of Active Benign Gastric Ulcer
Healing of NSAID-Associated Gastric Ulcer
In patients who continue NSAID use. Controlled studies did not extend beyond 8 weeks.
Risk Reduction of NSAID-Associated Gastric Ulcer

In patients with a history of a documented gastric ulcer who require the use of an NSAID. Controlled studies did not extend beyond 12 weeks.

Controlled studies did not extend beyond 12 weeks.

Gastneesphageal Reflux Dissas (GERD)

Short-Term Treatment of Symptomatic GERD

Short-Term Treatment (up to 8 weeks) of Erosive Esophagitis

For patients who do not heal with PREVACID for 8 weeks (5-10%), it may be helpful to give

an additional 8 weeks of treatment. If there is a recurrence of erosive esophagitis an
additional 8-week course of PREVACID may be considered.

Maintenance of Healing of Erosive Esophagitis Controlled studies did not extend beyond 12 mon

cal Hypersecretory Conditions Including Zollinger-Ellison Syndrome

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome
CONTRAINDICATIONS
PREVAIGID is contraindicated in patients with known hypersensitivity to any component of
the formulation of PREVAICID.
Amoxicillin is contraindicated in patients with a known hypersensitivity to any penicillin.
Clarithromycin is contraindicated in patients with a known hypersensitivity to
clarithromycin eyrhtromycin, and any of the macroidie antibiotics.
Concomitant administration of clarithromycin with cisapride, pimozdie, astemizole, or
terfenadine is contraindicated. There have been post-marketing reports of drug interactions
when clarithromycin and/or erythromycin are co-administered with cisapride, pimozdie,
astemizole, or terfenadine resulting in cardica arrhythmias (OT prolongation, vertricular
tachycardia, vertricular fibrillation, and torsades de pointsy most likely due to inhibition of
metabolism of these drugs by erythromycin and clarithromycin. Fatalities have been
reported.

(Please refer to full prescribing information for amoxicillin and clarithromycin before prescribing)

prescribing.)

WARNINGS

CLARITHROMYCIN SHOULD NOT BE USED IN PREGNANT WOMEN EXCEPT IN CLINICAL CIRCUMSTANCES WHERE NO ALTERNATIVE THERAPY IS APPROPRIATE. IF PREGNANCY OCCURS WHILE FANNE GLARITHROMYCIN, THE PATIENT SHOULD BE APPRISED OF THE POTENTIAL HAZARD TO THE FETUS. (SEE WARNINGS IN PRESCRIBING INFORMATION)
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PRECAUTIONS
General
Symptomatic response to therapy with lansoprazole does not preclude the presence of gastric malignancy.

yeastic intelligration, Information for Patients PREVACID is available as a capsule, orally disintegrating tablet and oral suspension, and is available in 15 mg and 30 mg strengths. Directions for use specific to the route and available methods of administration for each of these dosage forms is presented below. PREVACID should be taken before eating. PREVACID products SHOULD NOT BE CRUSHED OR CHEWED.

Phenylketonurics: Contains Phenylalanine 2.5 mg per 15 mg Tablet and 5.1 mg per 30 mg Tablet.

30 mg Tablet.
Administration Options
1. PREVACID Delayed-Release Capsules
PREVACID Delayed-Release Capsules
PREVACID Delayed-Release Capsules should be swallowed whole.
Atternatively, for patients who have difficulty swallowing capsules, PREVACID Delayed-Release Capsules can be opened and administered as follows:

Open capsule.
 Sprinkle intact granules on one tablespoon of either applesauce, ENSURE[®] pudding, cottage cheese, yogurt or strained pears.
 Swallow immediately.

PREVACID Delayed-Release Capsules may also be emptied into a small volume of either apple juice, orange juice or tomato juice and administered as follows:

- Open capsule:

puer capsule.

Sprinkle intact granules into a small volume of either apple juice, orange juice or tomato juice (60 mL – approximately 2 ounces).

Mix Driefly.

Wallow immediately.

Mix briefly.
Swallow immediately.
To ensure complete delivery of the dose, the glass should be rinsed with two or more volumes of juice and the contents swallowed immediately.

To ensure complete delivery of the dose, the glass should be rinsed with two or more volumes of juice and the contents swallowed immediately.

USE IN OTHER FOODS AND LIQUIDS HAS NOT BEEN STUDIED CLINICALLY AND IS THEREFORE NOT RECOMMENDED.

2. PREVACIO SoluTab bolughed-Release Orally Disintegrating Tablets
PREVACIO SoluTab bould not be chewed. Place the tablet on the tongue and allow it to disintegrate, with or without water, until the particles can be swallowed. The tablet typically disintegrates in less than 1 minute.

Alternatively, for children or other patients who have difficulty swallowing tablets, PREVACIO SoluTab can be delivered in two different ways.

PREVACIO SoluTab - Oral Syringe.
PREVACIO SoluTab - Cral Syringe and draw up approximately 4 mL of water, or place a 30 mg tablet in oral syringe and draw up approximately 4 mL of water, or place a 30 mg tablet in oral syringe and draw up approximately 10 mL of water.

Shake gently to allow for a quick dispersal.

After the tablet has dispersed, administer the contents within 15 minutes.

Refill the syringe with approximately 2 mL (5 mL for the 30 mg tablet) of water, shake gently, and administer any remaining contents.

PREVACID SoluTab – Nasogastric Tube Administration (≥ 8 French) or administration via a nasogastric tube, PREVACID SoluTab can be administered as To discharge the control of the cont

After the tablet has dispersed, inject unough the inject of the first that tablet has dispersed, inject unough the inject of the first tablet has dispersed in the inject of the first tablet has dispersed in the inject of the first tablet has dispersed in the inject of the first tablet has dispersed in the inject of the first tablet has dispersed, inject of the first tablet has dispersed, inject of the first tablet has dispersed, inject on the first tablet has dispersed in the first tablet has disp

tube.
3. PREVACID for Delayed-Release Oral Suspension
PREVACID for Delayed-Release Oral Suspension should be administered as follows:

pen packet.

b prepare a dose, empty the packet contents into a container containing 2 tablespoons of ATER. DO NOT USE OTHER LIQUIDS OR FOODS.

WALER. DO NOT USE OTHER LIQUIDS OR FOODS:

• Stir well, and drink immediately.

• If any material remains after drinking, add more water, stir, and drink immediately.

• This product should not be given through enteral administration tubes.

• This product should not be given through enteral administration tures. Drug Interactions
Lansoprazoli si metabolized through the cytochrome P₄₅₀ system, specifically through the
CYP3A and CYP2C19 isozymes. Studies have shown that lansoprazoli does not have
clinically significant interactions with other drugs metabolized by the cytochrome P₄₅₀
system, such as warfarin, antipyrine, indomethacin, ibuprofen, phenytoin, propranolof,
predissione, diseapean, or clariflymorphic in healthy subjects. These compounds are
metabolized through various cytochrome P₄₅₀ isozymes inciding CYP4R2, CYP2C9,
CYP2C19, CYP2C9, and CYP2A, When lansoprazole was administered concomitantly with
theophylline (CYP1R2, CYP2A), a major increase (10%) in the clearance of theophylline
clearance, this interaction is unlikely to be of clinical concern. Monetheless, individual
patients may require additional tration of their theophylline clearance,
and the concern additional tration of their theophylline clearance of the small magnitude and the inceptiviline does
started or stopped to ensure clinically effective blood levels.

clearance, this interaction is unlikely to be of clinical concern. Nonetheless, individual patients may require additional titration of their theophylline dosage when lansoprazole is started or stopped to ensure clinically effective blood levels.

In a study of healthy subjects neither the pharmacokinetics of warfarin enantiomers nor prothrombin time were affected following single or multiple 60 mg doses of lansoprazole. However, there have been reports of increased international Normalized Ratio (INR) and prothrombin time in patients receiving proton pump inhibitors, including lansoprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with proton pump inhibitors and warfarin concomitantly. Increases in INR and prothrombin time. Lansoprazole are done to the monitored for increases in INR and prothrombin time. Lansoprazole has also been shown to have no clinically significant interaction with amoxicillin. In a single-dose crossover study examining lansoprazole 30 mg and omeprazole 20 mg each administered alone and concomitantly with sucraflate 1 gram, absorption of the proton pump inhibitors should be taken at least 30 minutes prior to sucraflate. In clinical trials, antacids were administered concomitantly with PREVACID Delayed-Release Capsules; this did not interfere with its effect.

Lansoprazole causes a profound and long-lasting inhibition of gastric acid secretion; therefore, it is theoretically possible that lansoprazole may interfere with the absorption of trugs where gastric pit is an important determinant of bioavailability (e.g., ketoconazole, ampicillin esters, iron salts, digoxin).

Carcinogenesis, Mutagenesis, Impairment of Fertility

In two 24-month carcinogenicity studies. Sprague-Dawley rats were treated orally with doses of 5 to 150 mg/kg/dy 4, but of 40 times the economended human dose dose-related increase of testicular interstitial cell adenomas. The incidence of these adenomas in rats receiving doses of 15 t

ou myragroay (13 times the recommended human dose based on body surface area) in a 1-year toxicity study. In a 24-month carcinogenicity study, CD-1 mice were treated orally with doses of 15 to 600 mg/kg/day, 2 to 80 times the recommended human dose based on body surface area. Lansoprazole produced a dose-retated increased incidence of gastric EC. cell hyperplasia. It also produced an increased incidence of liver tumors (hepatocellular adenoma plus carcinoma). The tumor incidences in male mice treated with 800 and 600 mg/kg/day (80 to 80 times the recommended human dose based on body surface area) and female mice treated with 150 to 600 mg/kg/day (20 to 80 times the recommended human dose based on body surface area) exceeded the ranges of background incidences in historical controls for this strain of mice. Lansoprazole treatment produced adenoma of rete testis in male mice receiving 75 to 600 mg/kg/day (10 to 80 times the recommended human dose based on body surface area).

body surface area).

Lansoprazole was not genotoxic in the Ames test, the *ex vivo* rat hepatocyte unscheduled DNA synthesis (UDS) test, the *in vivo* mouse micronucleus test or the rat bone marrow cell chromosomal aberration test. It was positive in *in vitro* human lymphocyte chromosomal aberration assays.

chromosomal aberration test. it was pusing in an aberration assays.

Lansoprazole at oral doses up to 150 mg/kg/day (40 times the recommended human dose based on body surface area) was found to have no effect on fertility and reproductive performance of male and female rats.

Pregnancy Teratogenic Effects.

Pregnancy Category B

Lansoprazole Teratology studies have been performed in pregnant rats at oral doses up to 150 mg/kg/day (40 times the recommended human dose based on body surface area) and pregnant rabbits at oral doses up to 30 mg/kg/day (16 times the recommended human dose based on body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to

lansoprazole.

There are, however, no adequate or well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. gnancy Category C

See **WARNINGS** (above) and full prescribing information for clarithromycin before using in

ursing Mothers ansoprazole or its metabolites are excreted in the milk of rats. It is not known whether insoprazole is excreted in human milk. Because many drugs are excreted in human milk, ecause of the potential for serious adverse reactions in nursing infaints from lansoprazole, nd because of the potential for tumorigenicity shown for lansoprazole in rat carcinogenicity tuties, a decision should be made whether to discontinue nursing or to discontinue the rug, taking into account the importance of the drug to the mother.

drug, taxing into account the importance or the drug to the mother.
Prediatric Use
The safety and effectiveness of PREVACID have been established in pediatric patients 1 to
Ty years of age for short-term treatment of symptomatic GERD and erosive esophagitis. Use
of PREVACID in of this population is supported by evidence from adequate and well-controlled
studies of PREVACID in adults with additional clinical, pharmacokinetic, and
pharmacodynamic studies performed in pediatric patients. The adverse events profile in
pediatric patients is similar to that of adults. There were no adverse events reported in
Scilinical studies that were not previously observed in adults. The safety and effectiveness of
PREVACID in patients <1 year of age have not been established.

1to 11 years of age
The pediatric safety of PREVACID Delayed-Release Capsules has been assessed in
65 pediatric patients aged 1 to 11 years of age. Of the 66 patients with GERD 85% (66/66)
took PREVACID for 8 weeks and 15% (10/66) took it for 12 weeks.
The most frequently reported (2 or more patients) treatment-related adverse events in
patients 1 to 11 years of age (N=66) were constipation (5%) and headache (3%).

patients 1 to 11 years of age (N=ob) were consuperuru (2%) and unequence (2%).

2 to 17 years of age

The safety of PREVACID Delayed-Release Capsules has been assessed in these

7 adolescent patients, of the 87 adolescent patients with GERD, 6% (587) took PREVACID

for -6 weeks, 93% (8187) for 6-10 weeks, and 1% (1/87) for -10 weeks.

The most frequently reported (at least 3%) treatment-related adverses events in these
patients were headache (7%), abdominal pain (5%), nausea (3%) and dizziness (3%),

Treatment-related dizziness, reported in this package insert as occurring in c1% of adult

patients, was reported in this study by 3 adolescent patients with noncrosive GERD, who had dizziness concurrently with other events (such as migraline, dyspnea, and vomitting).

Use in Women

Over 4,000 women were treated with lansoprazole. Ulcer healing rates in females were similar to those in males. The incidence rates of adverse events were also similar to those

Use in Geriatric Patients
Ulcer healing rates in elderly patients are similar to those in a younger age group. The

incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in younger patients. For elderly patients, dosage and administration of lansoprazole need not be altered for a particular indication.

ADVERSE REACTIONS
Clinical

initial ordividid, over 10,000 patients have been treated with lansoprazole in Phase 2-3 clinical ordividide, over 10,000 patients have been treated with lansoprazole in Phase 2-3 clinical las involving various dosages and durations of treatment. The adverse reaction profiles for EVACID Delayed-Release Capsules and PREVACID for Delayed-Release Vola Suspension smallar. In general, lansoprazole treatment has been well-folerated in both short-term to following adverse events were reported by the treating physician to have a possible or bable relationship to drug in 1% or more of PREVACID-treated patients and occurred at reater rate in PREVACID-treated patients than placebo-treated patients. Incidence of Prossibly or Probably Treatment-Related Adverse Events in Short-Tam, Placebo-Controlled Studies

	PREVACID	Placebo
	(N= 2768)	(N= 1023)
Body System/Adverse Event	%	%
Body as a Whole		
Abdominal Pain	2.1	1.2
Digestive System		
Constipation	1.0	0.4
Diarrhea	3.8	2.3
Mauren	1.2	1.0

Nausea

1.2

Headache was also seen at greater than 1% incidence but was more comon placebo. The incidence of diarrhea was similar between patients who received placebo and patients who received lansoprazole 0.15 mg and 30 mg, but higher in the patients who received lansoprazole 0.70 mg (2.9%, 1.4%, 4.2%, and 7.4%, respectively). The most commonly reported possibly or probably treatment-related adverse event during maintenance therany was diarrhea.

Interpretation of the graph (PARY ASS), and a second of the graph of t

of diarrhea for patients treated with PREVACID was 5%, misoprostol 22%, and placebo 3%. Additional adverse experiences occurring in c.1% of patients or subjects in domestic trials are shown below. Refer to Postmarketing for adverse reactions occurring in c.1% of patients or subjects in domestic trials are shown below. Refer to Postmarketing for adverse reactions occurring since the drug was marketed.

**Body as a Whole – abdomen entarged, allergic reaction, asthenia, back pain, candidiasis, carcinoma, chest pain (not otherwise specified), chills, edema fever, flu syndrome, halitosis, infection (not otherwise specified), malaise, neck pain, neck rigidity, pain, pelvic pain; **Carcilovascular System – angina, arrhythmia, bradycardia, cerebrovascular accident/ocrebral infarction, flugerentson/hypotension, migralne, moycardial infarction, palpstantson, shock (circulatory failure), syncope, tactiycardia, vasoodilation, **Digestive System – abnormal infarction, flugerentson/hypotension, migralne, myocardial mistration, applications, shock (circulatory failure), syncope, tactiycardia, vasoodilation, **Digestive System – abnormal discoloration, flatulence, gastric nodules/fundic gland polyps, gastrifis, gastrometeritis, gastrointestinal anomaly, gastrointestinal discorder, gastrointestinal hemorrhage, glossitis, gum hemorrhage, hematemesis, increased appetite, increased aslaviation, melan, moutulceration, nausea and vomiting, nausea and vomiting and diarrhea, oral moniliasis, rectal and Lymphatic System – ashmal, hemolysis, hymphatenopathy, Metabolic and Mutritional Disorders – gout, delivoration, they peptite, increased algority, Metabolic and Mutritional Disorders – gout, delivoration, theyenghicemia/hypoglycemia, peripheral edema, weightion, and sunda produces and supplications, and produces and sunda produces

Postmarketing
On-going Satety Surveillance: Additional adverse experiences have been reported since lansoprazole has been marketed. The majority of these cases are foreign-sourced and a relationship to lansoprazole has not been established. Because these events were reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events are listed below by COSTART body system.

voluntarily from a population of unknown size, estimates of frequency cannot be made. These events are listed believe by CDSTART body system. A population of unknown size, estimates of frequency cannot be made. These events are listed believe by CDSTART body system - appraisotoxicity, pancreatilis, vomiting; Hemic and Lymphatic System - agranulocytosis, aplastic anemia, hemolytic anemia, leukopenia, pancrylopenia, pancrylo

Laboratory Values
The following changes in laboratory parameters for lansoprazole were reported as adverse

events:
Abnormal liver function tests, increased SGOT (AST), increased SGPT (ALT), increased creatinine, increased alkaline phosphatase, increased globulins, increased GGTP, increased/decreased/abnormal WBC, abnormal AB ratio, abnormal ABC, billirotinemia, eosinophilia, hyperlipemia, increased/decreased electrolytes, increased/abcreased cholesterol, increased gulocoorticoids, increased LDH, increased/decreased/abnormal patients, and increased gastine levels. Urine abnormalities such as abuminuria, glycosuria, and hematuria were also reported. Additional isolated laboratory abnormalities were reported.

and hematuria were also reported. Additional isolated laboratory abnormalities were reported.

In the placebo controlled studies, when SGOT (AST) and SGPT (ALT) were evaluated, 0.4% (4)978) placebo patients and 0.4% (11/2677) lansoprazole patients had enzyme elevations greater than three times the upper limit of normal range at the final treatment visit. None of these lansoprazole patients reported jaundice at any time during the study. In clinical trials using combination therapy with PREVACID plus amoxicillin, and arithromycin, and PREVACID plus amoxicillin, no increased laboratory abnormalities particular to these drug combinations were observed. For more information on laboratory value changes with amoxicillin or clarithromycin, refer to their package inserts, ADVERSE REACTIONS section.

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Ensoure: Is a registered trademark or Journal Laboratories.

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For more detailed information, see full prescribing information or contact TAP Medical Information at 1-800-622-2011.

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