CLINICAL

Aneuploidy Risk Assessed

Women who have had three spontaneous abortions before a current pregnancy have almost a 50% higher risk of carrying a fetus with aneuploidy than those who've never had a miscarriage, according to a large review of women who had undergone amniocentesis.

The aneuploidy rate becomes almost 2% in women who have had three pregnancy losses, Katherine Bianco, M.D., and her associates wrote in a poster presentation at the annual meeting of the Society for Maternal-Fetal Medicine.

The study reviewed fetal karyotype analyses from 46,939 women seen at a single prenatal diagnostic referral center between 1983 and 2003, 80% of whom were 35 years old or older, said Dr. Bianco at the University of California, San Francisco.

CAPSULES

According to those records, women who could identify one previous spontaneous abortion were found to have fetuses with trisomy 13, 18, or 21 at a rate of 1.45%, compared with a rate of 1.10% for those who had not previously had a spontaneous abortion. Women who had two prior losses had a rate of 1.56%. Those

with three prior losses had a rate of 1.70%, and a 2.18% rate of any aneuploidy.

Because the review found an escalating rate with each additional known pregnancy loss, the study needs to be replicated to see if this holds true for younger women, Dr. Bianco said in an interview.

Essure Safe for at Least 5 Years

Hysteroscopic sterilization with Essure microinserts appears safe and effective for at least 5 years after the procedure, according to a poster presented by John F. Kerin, M.D., at the annual meeting of the American College of Obstetricians and Gynecologists.

Dr. Kerin of Flinders Medical Centre, Adelaide, Australia, and his colleagues from the Selective Tubal Occlusion Procedure 2000 Investigators Group followed 643 women for up to 5 years after they underwent the procedure. All women had received bilateral placements of Essure microinserts as part of phase II or phase III clinical trials sponsored by Conceptus Inc., the device's manufacturer.

Not a single pregnancy occurred in 29,357 woman-months of follow-up, Dr. Kerin reported. The age-adjusted cumulative bayesian effectiveness rate at 5 years was 99.74%

Patient tolerance, comfort, and satisfaction were measured at seven or eight visits during the follow-up period. At all visits, 99% of women rated their tolerance of Essure as "good" or "excellent," 99% rated their comfort as "good" or "excellent," and 97% rated their satisfaction as "satisfied" or "very satisfied." No women reported persistent pain or bleeding.

NuvaRing Has Low Expulsion Rate

In a year's experience with the NuvaRing contraceptive, only 2.3% of women had an expulsion of the device, according to the pooled results of four large, phase III clinical trials, Marc Kaptein, M.D., and Edio Zampaglione, M.D., reported in a poster presentation at the annual meeting of the American College of Obstetricians and Gynecologists.

In a retrospective analysis of 3,333 women and 33,462 cycles, expulsion occurred in only 0.5% of cycles, according to the investigators, who were from Organon International Inc., Roseland, N.J. Organon is the manufacturer of NuvaRing.

The proportion of cycles with expulsions decreased over time, an effect the investigators attributed to users' increasing experience with the NuvaRing. During the first three cycles, 1.7% of women experienced an expulsion. The studies followed the women for 13 cycles. During the 11th, 12th, and 13th cycles, only 0.2% of women experienced expulsions.

Surgery for Brachial Plexus Injuries

Surgery is the best option for treatment in children with global brachial plexus birth palsies, according to one study.

Final shoulder function in 36 infants with such injuries who underwent surgery was fair in 22% of patients, satisfactory in 50%, good in 22%, and excellent in 6%. Final shoulder function was poor in 100% of 12 control patients who did not undergo surgery, Patricia DiTaranto, M.D., said at the annual meeting of the American Association for Hand Surgery.

Hand function in the surgery patients was fair in 19%, satisfactory in 58%, good in 17%, and excellent in 6%. Hand function in controls was poor in 25% and fair in 75%, said Dr. DiTaranto of Miami Children's Hospital.

Function was assessed with the Gilbert-Raimondi system, she noted. The children studied were born at a single institution over a 4-year period and were followed for at least 2.5 years. All had global brachial plexus injuries at birth, and the clinical findings persisted at 6-month follow-up.

The goal of the surgical reconstruction of the brachial plexus was to recover shoulder stability and hand function, she said.

-From staff reports

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

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

PREVACID® (lansoprazole) For Delayed-Release Oral Suspension PREVACID® SoluTab™ (lansoprazole) Delayed-Release Orally

Disintegrating Tablets

RX ONIY

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

Dishinejavania faulise ain Pricevolor voi belagerenease ora dispension ale miticateu for:

Short-Term Treatment (4 weeks) of Active Diodenal Ulcer
R. pylari Faradication to Reduce the Risk of Diodenal Ulcer Recurrence
Triple Therapy: PREVACID/amoxicillin
Dual Therapy: PREVACID/amoxicillin
Who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected.

Maintenance of Healed Diodenal Ulcers
Controlled studies do not extend beyond 12 months.

Short-Term Treatment (up to 8 weeks) of Active Benign Gastric Ulcer
Healing of NSAID-Associated Gastric Ulcer
In patients with 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.
Gastroesophageal Rellux Disease (GERD) In patients with a history of a documented gastric Controlled studies did not extend beyond 12 weeks. Gastroesophageal Reflux Disease (GERD) Short-Term Treatment of Symptomatic GERD

Gastriesopnageal Heliux Usease (GEHD)
Short-Term Treatment of Symptomatic GERD
Short-Term Treatment (by to 8 weeks) of Frosive 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 weeks of treatment. If there is a recurrence of erosive esophagitis 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 months.

Pathological Phyeroscretory Conditions Including Zollinger-Ellison Syndrome

CONTRAINDICATIONS
PREVACID is contraindicated in patients with known hypersensitivity to any component of
the formulation of PREVACID.

CONTRAINDICATIONS

PREVACID is contraindicated in patients with known hypersensitivity to any component of the formulation of PREVACID.

Amoxicillin is contraindicated in patients with a known hypersensitivity to any penicillin. Clarifromycin is contraindicated in patients with a known hypersensitivity to clarifromycin is contraindicated in patients with a known hypersensitivity to clarifromycin eyithomycin, and any of the macrolide antibiotics.

Concomitant administration of clarifromycin with cisapride, primozide, astemizole, or terfenadine is contraindicated. There have been post-marketing reports of drug interactions when clarifromycin and/or eyifromycin and/oradycin, and torsades de pointes) most likely due to inhibition of metabolism of these drugs by erythromycin and clariftromycin. Fatalities have been reported.

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

WARNINGS

CLARITHROMYCIN SHOULD NOT BE USED IN PREGNANT WOMEN EXCEPT IN CLINICAL CIRCUMSTANCES WHERE NO ALTERNATIVE THERAPY IS APPROPRIATE. IF PREGNANCY OCCURS WHILE TAKING CLARITHROMYCIN THE PATIENT SHOULD BE APPRISED OF THE POTENTIAL HAZARD TO THE FETUS. (SEE WARNINGS IN PRESCRIBING INFORMATION FOR CLARITHROMYCIN.)

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including clarithromycin and amoxicillin, and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarnea subsequent to the administration of amibacterial agents. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of "antibiotic-sasciciated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis. Serious and occasionally fatal hypersensitivity (analyniscic) reactions have been reported in patients on penicillin hypersensitivity and/or a history of penicillin, careful inquiry reactions who have experienced severe hypersensitivity reactions who remaid the appropriate therapy instituted.

SERIOUS ANAPHYLACTIC REACTIONS REQUIRE IMMEDIATE EMPRENCY TREATMENT WITH PRINEPRINE. OXYGEN, INTRAVENOUS STEROIDS. AND AIRWAY MANAGEMENT, INCLUDING INTUBATION,

PRECAUTIONS

General
Symptomatic response to therapy with lansoprazole does not preclude the presence of gastric malignancy.
Information for Patients
PREVACID is available as a capsule, orally disintegrating tablet and oral suspension, and is available in 15 mg and 30 mg streptls. 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.

PREVACID Delayed-Release Capsules
 PREVACID Delayed-Release Capsules should be swallowed whole

Alternatively, for patients who have difficulty swallowing capsules, PREVACID Delayed-Release Capsules can be opened and administered as follows: - Done capsules re. act granules on one tablespoon of either applesauce, ENSURE[®] pudding, ese, yogurt or strained pears.

Cottage cheese, yogurt or strained pears.

Swallow immediately,

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

pple juice, orange juice or tomato juice and administered as follows:

Open capsule.

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

Mix briefly.

Note unionly.

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.

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

2. PREVACID SoluTab Delayed-Release Orally Disintegrating Tablets

PREVACID Solutab should 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.

disintegrates in less than 1 minute.

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

PREVACID Solutab - Oral Syringe, PREVACID Solutab can be administered as follows:

Prevacid Solutab - 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.

Felfill the syringe with approximately 2 mL (6 mL for the 30 mg tablet) of water, shake gently, and administer any remaining contents.

PREVACID SoluTab – Nasogastric Tube Administration (c 8 French)
For administration via a nasogastric tube, PREVACID SoluTab can be administered as
follows:
Place a 15 mg tablet in a syringe and draw up 4 mL of water, or place a 30 mg tablet in a
syringe and draw up 10 mL of water.
Shake gently olallow for a quick dispersal.
- After the tablet has dispersed, inject through the nasogastric tube into the stomach within
15 minutes.

15 minutes. Refill the syringe with approximately 5 mL of water, shake gently, and flush the nasogastric

University of the Control of the Control

Open packet.

To prepare a dose, empty the packet contents into a container containing 2 tablespoons of WATER. 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.
 Drug Interactions

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

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

Drug Interactions

Lansoprazole is metabolized through the cytochrome P₄₅₀ system, specifically through the CYP2A and CYP2C19 isozymes. Studies have shown that lansoprazole does not have clinically significant interactions with other drugs metabolized by the cytochrome P₄₅₀ system, such as warfarin, antipyrine, indomethacin, ibuprofen, phenytoin, propranolol, predisione, diazepam, or lacintromycin in healthy subjects. These compounds are metabolized through various cytochrome P₄₅₀ isozymes including CYP1A2, CYP2C9, CYP2C19, CYP2C9, and CYP3A3. When lansoprazole was administered concomitantly with theophylline (CYP1A2, CYP3A), a minor increase (10%) in the clearance of theophylline was seen. Because of the small magnitude and the direction of the effect on theophylline vascem. Because of the small magnitude and the direction of the effect on theophylline detarance, this interaction is unlikely to be of clinical concern. Monetheless, individual patients may require additional titration of their theophylline dosage when lansoprazole started or stopped to ensure clinically effective blood levels.

In a study of healthy subjects neither the pharmacokinetics of warfarin enantiomers no rothrombin 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 with sucreates a language of the proton pump inhibitors was delayed and their bioavailability was reduced by 17% and 16%, respectively, when administered concomitantly with sucreates. In clinical trials, antacids were administered con

Carcinogenesis, Mutagenesis, Impairment of Fertility
In two 24-month carcinogenicity studies, Sprague-Dawley rats were treated orally with
doses of \$10 150 mg/kg/day, about \$1 to 40 times the exposure on a body surface (mg/m²)
basis, of a 50-kg person of average height (1.46 m² body surface area) given the
recommended human dose of 30 mg/day (22.2 mg/m²). Lansporazole produced doserelated gastric enterochromaffin-like (ECI) cell hyperplasia and ECI. cell carcinoids in both
male and female rats. It also increased the incidence of intestinal metaplasia of the gastric
epithelium in both sexes. In male rats, lansoprazole produced a dose-related increase of
testicular interstitial cell adenomas. The incidence of these adenomas in rats receiving doses
of 15 to 150 mg/kg/day (14 to 40 times the recommended human dose based on body
surface area) exceeded the low background incidence (range = 1.4 to 10%) for this strain of
tal. Testicular interstitial cell adenoma also occurred in 1 of 30 rats treated with
50 mg/kg/day (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 dness of 15 to600 mg/kg/day (24 to 60 times).

30 mg/kg/day (13 mms ter recommended numan dose based on body surface area) in a ryear 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-related increased incidence of gastric ECL cell hyperplasia, lit also produced an increased incidence of liver tumors (hepatocellular adenoma pusc carcinoma). The tumor incidences in male mice treated with 300 and 600 mg/kg/day (40 to 80 times the recommended human dose based on body surface area) and female incete 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 or 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).

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

omosomal appriation is the production of the production and the productive formance of male and female rats.

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

nsoprazole

attology studies have been performed in pregnant rats at oral doses up to 150 mg/kg/day

1 times the recommended human dose based on body surface area) and pregnant rabbits

ard doses up to 30 mg/kg/day (16 times the recommended human dose based on body

rface area) and have revealed no evidence of impaired fertility or harm to the fetus due to

soorazole.

Isoprazole.

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

gnancy Category C

arithromycin

pregnant women.

Mursing Mothers

Lansoprazole or its metabolites are excreted in the milk of rats. It is not known whether
lansoprazole is excreted in human milk. Because many drugs are excreted in human milk,
because of the potential for serious adverse reactions in nursing infants from lansoprazole,
and because of the potential for tumorigenicity shown for lansoprazole in rat carcinogenicity
studies, a decision should be made whether to discontinue nursing or to discontinue the
drug, taking into account the importance of the drug to the mother.

drug, taking into account use importance or Pediatric Use. Prediatric Use. The safety and effectiveness of PREVACID have been established in pediatric patients 1 to 17 years of age for short-term treatment of symptomatic GERD and erosive esophagitis. Use of PREVACID in this population is supported by evidence from adequate and vell-controlled studies of PREVACID in adults with additional clinical, pharmacokinetic, and pharmacodynamic studies performed in pediatric patients. The adverse events profitel in pediatric patients is similar to that of adults. There were no adverse events reported in Use clinical studies that were not previously observed in adults. The safety and effectiveness of PREVACID in patients <1 year of age have not been established.

PREVACIO In patients 1 your company. In to 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 65 patients with GERD 85% (56/65) took PREVACID for 8 weeks and 15% (10/66) took if to 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%).

The most frequently tripution to patients to 11 years of age (N=66) were constipation (3%) and requence.

12 to 17 years of age
The safety of PREVACID. Delayed-Release Capcules has been assessed in these 37 adolescent patients. Of the 87 adolescent patients with GERD, 6% (5/87) took PREVACID for 46 weeks, 93% (8/87) for 5-10 weeks.

The most frequently reported (at least 4%) treatment-related adverse events in these patients were headache (7%), abdominal pain (5%), nausea (3%) and dizziness (3%) and treatment-related adverses events in these patients were headache (7%), abdominal pain (5%), nausea (9%) and dizziness (3%) of adult patients, was reported in this study by 3 adolescent patients with nonerosive GERD, who had dizziness concurrently with other events (such as migrariae, oxyspinea, 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 seen in males.

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

ADVERSE REACTIONS Clinical Clinical
Worldwide, over 10,000 patients have been treated with lansoprazole in Phase 2-3 clinic
Worldwide, over 10,000 patients have been treated with lansoprazole in Phase 2-3 clinic
trials involving various dosages and durations of treatment. The adverse reaction profiles t
PREVACID belayed-Release Capsules and PREVACID for Delayed-Release Oral Suspensi
are similar. In general, lansoprazole treatment has been well-locleated in both short-ter
and long-term trials.

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.

s.
s.
sree events were reported by the treating physician to have a possible or ip to drug in 1% or more of PREVACID-treated patients and occurred at EVACID-treated patients:
Incidence of Possibly or Probably

Incidence of Possibly or Probably

Treatment-Related Adverse Events in Short-Term, Placebo-Controlled Studies	
PREVACID	Placebo
(N= 2768)	(N= 1023)
%	%
2.1	1.2
1.0	0.4
3.8	2.3
1.3	1.2
	PREVACID (N= 2768) % 2.1 1.0 3.8

Jache was also seen at greater than 1% incidence but was more common on placebo, incidence of diarrhea was similar between patients who received placebo and patients received lansoprazole 15 mg and 30 mg, but higher in the patients who received oprazole 60 mg (2.9%, 1.4%, 4.2%, and 7.4%, respectively).

most commonly reported possibly or probably treatment-related adverse event during

ansoprazole 60 mg (2.9%, 1.4%, 4.2%, and 7.4%, respectively). The most commonly reported possibly or probably treatment-related adverse event during maintenance therapy was diarrhea. In the risk reduction study of PREVACID for NSAID-associated gastric ulcers, the incidence of diarrhea for patients treated with PREVACID was 5%, misoprostol 22%, and placebo 3%. Additional adverse experiences occurring in <1% of patients or subjects in domestic trials are shown below. Refer to **Postmarketing** for adverse reactions occurring since the drug was marketed.

Additional adverse experiences occurring in c1*% or plantens 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 enlarged, allergic reaction, asthenia, back pain, candidiasis, carcinoma, chest pain (not otherwise specified), chilis, edema, fever, flu syndrome, halitosis, infection (not otherwise specified), malaise, neck pain, neck rigidity, pain, pelvic pain; Cardiovascular System – angina, arrhythmia, bradycardia, cerebrovascular accident/cerebral infarction, hypertension/hypotension, migraine, myocardial infarction, palpitations, shock (circulatory failure), syncope, tachycardia, vasodilation; Digestive System – abnormal stools, anorexia, bezoar, cardiopspam, choletihiasis, colitis, dry mouth, dyspepsia, dysphagia, enteritis, eructation, esophageal stenosis, esophageal ulcer, esophagitis, fecal dysphagia, enteritis, eructation, esophageal stenosis, esophageal ulcer, esophagitis, fecal dysphagia, enteritis, estric nodules/fundio gland polysy, gastritis, gastrointestinal anomaly, gastrointestinal disorder, gastrointestinal anomaly, gastrointestinal disorder, gastrointestinal anomaly, gastrointestinal disorder, gastrointestinal anomaly, gastrointestinal disorder, gastrointestinal hemorrhage, clossitis, gum hemorrhage, increased appetite, increased aslaviation, melena, mouth ulceration, nausea and vorniting, nausea and vorniting and diarrhea, oral moniliasis, rectal and lymphatic System – anham, hemolysis, bymphadenopathy, Metabolic and Nutritional Disorders – gout, dehydration, hyperdycemia/hypodycemia, peripheral edema, weight pain/loss. Musculoskeletal System – arthralia, arthritis, bone disorder, joint disorder, legicarion, manais, arawiely, apathy, contision, convolusion, depersainal and Appandages – acne, alopecia, contact dermatitis, dry skin, fixed eruption, harder experiatory inflamental proton, byset eruption, speripheral proton, proton, taste loss, taste perversion, timmitus, visual field defect,

erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (some fatal); Special Senses-speech disorder, Uragenial System- urinary retetion. Combination Therapy with Amoxicillin and Clarithromycin

In clinical trials using combination therapy with PREVACID plus amoxicillin and clarithromycin, and PREVACID plus amoxicillin, no adverse reactions peculiar to these drug combinations were observed. Adverse reactions that have occurred have been limited to those that had been previously reported with PREVACID, amoxicillin, or clarithromycin.

Triple Therapy: PREVACID/amoxicillin/clarithromycin

Triple Therapy: PREVACID/amoxicillin/clarithromycin

The most frequently reported adverse events for patients who received triple therapy for 14 days were diarrhea (7%), headache (6%), and taste perversion (5%). There were not satistically significant differences in the frequency of reported adverse events between the 10- and 14-day triple therapy regimens. No treatment-emergent adverse events were observed at significantly higher rates with triple therapy than with any dual therapy regimen. The most frequently reported adverse events between the state of the presence of the prese

events:
Abnormal liver function tests, increased SGOT (AST), increased SGPT (ALT), increased SGOT (ast), increased silkaline phosphatase, increased globulins, increased GGTP, increased/alkaline phosphatase, increased globulins, increased GGTP, increased/decreased/abnormal WBC, abnormal AG ratio, abnormal ABC, bilirubinemia, eosinophilia, hyperlipemia, increased/decreased electrolytes, increased/decreased/abnormal platelets, and increased glococorticoids, increased LDH, increased/decreased/abnormal platelets, and increased gatorine review. Unreased platelets, and increased gatorine review. Unreased platelets, and increased gatorine globuline reported. Additional isolated laboratory abnormalities were reported.

reported. In the placebo controlled studies, when SGOT (AST) and SGPT (ALT) were evaluated, 0.4% (4/97R) nlacebo patients and 0.4% (11/2677) lansoprazole patients had enzyme elevations

OVERDOSAGE

Oral doses up to 5000 mg/kg in rats (approximately 1300 times the recommended human dose based on body surface area) and mice (about 675.7 times the recommended human dose based on body surface area) did not produce deaths or any clinical signs. Lansoprazole is not removed from the circulation by hemodalysis, in one reported case of overdose, the patient consumed 600 mg of lansoprazole with no adverse reaction.

overoose, the patient consumed but mo of lansoprazole with no adverse reaction.

Distributed by TAP Pharmaceuticals Inc.
Lake Forest, It. 60045, U.S.A.

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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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