singled out federal funding for abstinence-

only education as an example of a strate-

in the Cochrane Review, for example, re-

viewed eight published randomized con-

trolled trials of abstinence-only programs,

compared with standard sex education

or safe-sex programs, involving 13,191

none of the abstinence-only programs demonstrated a significant decline in self-

reported sexual activity or any biological

outcome such as pregnancy or diagnosis

with a sexually transmitted disease (STD),

compared with the other approaches, said

Dr. Jaffe at the conference, sponsored by the

Foundation for Retrovirology and Human

A recent University of Pennsylvania

study of 662 African American children

(median age, 12 years) did show significantly less sexual activity among those re-

ceiving abstinence-only education, com-

pared with those exposed to other interventions; even so, nearly a third of the virgins in the abstinence-only group became sexually active over the course of the

Dr. Jaffe said it cannot be entirely ruled out that abstinence-only education could benefit "very specific groups," but the preponderance of evidence suggests it is

By contrast, he pointed to condom promotion, shown to be "highly efficacious" in preventing HIV transmission, and nee-

dle- and syringe-exchange programs, which demonstrate at least modest evi-

dence of reducing intermediate-level activities with the capacity to spread HIV, as

Condom distribution campaigns are currently being opposed by individuals

President Bush's proposed 2007 budget includes \$204 million in support of absti-

who believe availability will undermine ab-

nence-only education, while "no adminis-

tration, Democrat or Republican, has ever put any [federal] money whatsoever into needle-exchange programs in this country,

in contrast to many other countries, in-

Purely behavioral interventions, pri-

marily skill-building sessions aimed at re-

ducing risky activities among high-risk individuals, are highly significantly

efficacious in reducing unprotected sex

Finally, HIV testing by itself is a pro-

found risk-reducing strategy, because individuals who learn they have been ex-

posed to the virus sharply reduce

behaviors that could lead to transmission

Public health prevention strategies can go only so far in curbing the epidemic,

emphasized Dr. Jaffe, particularly when it

However, some indicators suggest that resources must be quickly marshaled to

stem a rising tide of cases, especially

among men who have sex with men and among African Americans and other eth-

comes to sexual behavior change.

cluding the U.K.," Dr. Jaffe said.

and acquiring STDs, he said.

to others, he noted.

nic minorities.

more effective approaches.

stinence-only programs.

With a median follow-up of 12 months,

American youths.

Health.

2-year study.

not efficacious.

A "very comprehensive" study in press

gy based on beliefs rather than science.

Expert Warns of Ominous Signs in AIDS Fight

BY BETSY BATES Los Angeles Bureau

LOS ANGELES — The number of Americans diagnosed with AIDS is now approaching the 1 million mark, with more than a half-million deaths since the epidemic began and 17,000 more people dying of the disease each year, Dr. Harold Jaffe said during a plenary session at the 14th Conference on Retroviruses and Opportunistic Infections.

That mortality-58 per million-is "twice as high as any country in the European Union and 10 times as high as in the United Kingdom," said Dr. Jaffe, former director of HIV prevention for the Centers for Disease Control and Prevention and currently head of the department of public health at Oxford University, England.

A troubling jump in incidence in 2005, the latest year for which data are available points to the critical need for community

leadership, personal responsibility, and support of preventive efforts proven to work, he said.

The need for treatment is critical, but I agree with my colleague Dr. Kevin De Cock [WHO director of HIV/AIDS] that we are not going to be able to treat our way out of this epidemic."

"I guess it seems obvious that we should be implementing what works, evaluating what might work, and stop trying to do what doesn't work," added Dr. Jaffe, who

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

- $\label{eq:prevacide} PREVACID^{\textcircled{B}} \mbox{ (lansoprazole) Delayed-Release Capsules}$
- PREVACID[®] (lansoprazole) For Delayed-Release Oral Suspension

PREVACID® SoluTabTM (lansoprazole) Delayed-Release Orally

egrating Tablets

Rx only

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

for: Short-Term Treatment (4 weeks) of Active Duodenal Ulcer H. pylord Fradication to Reduce the Risk of Duodenal Ulcer Recurrence Triple Therapy: PEVACIDiamoxicillinkdarithromycin Duia Therapy: PEVACIDiamoxicillink Who are either allergic or intolerant to clarithromycin or in whom resistance clarithromycin to shown or suspected.

Maintenance of Healed Duodenal Ulcers Controlled studies do not extend beyond 12 months. Short-Term Treatment (up to 8 weeks) of Active Benign Gastric Ulcer

Short-Ferm 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 haitosy of a documented gastric ulcer who require the use of an NSAID. Controlled studies did not extend beyond 12 weeks. Gastroesophageal Refut Disease (GERD) Short-Ferm Treatment (up to 8 weeks) of Erosive Esophagitis For patients who do not heal with PREVACID for 8 weeks () for soive Esophagitis an additional 8-week course of PREVACID for 8 weeks () for soive of erosive esophagitis an additional 8-week course of PREVACID may be considered.

an auusuna o weeks or treatment. If there is a recurrence of erosive esophagitis an additional 3-week course of PREVACID may be considered. Maintenance of Healing of Erosive Esophagits Controlled studies did not extend beyond 12 months. Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome CONTRAINDICATIONS PREVACID is contraindicated in patients with known hypersensitivity to any component of the formulation of PREVACID. Amoxicillin is contraindicated in patients with known hypersensitivity to any penicillin. Concomitant administration of clarithromycin with cisaprice, primozide, astemizole, or terfenadine is contraindicated. There have been post-marketing reports of drug interactions when clarithromycin, and any of the macrolide antibiotics. Concomitant administration or Horthormycin acconding in condimision with cisaprice, primozide, astemizole, or terfenadine resulting in cardiac arrhythmias (OT prolongation, ventricular tachycardia, ventricular fibrillation, and torsades de pointes) most likely due to inhibition of reported. [Please refer to full prescribing information for amoviellin and elaytithromycin bacters.

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

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

ARITHROMVCIN.) omembranous colitis has been reported with nearly all antibacterial agents, ge clarithromycin and amozicillin, and may range in severity from mild to life hing. Therefore, it is important to consider this diagnosis in patients who present rimthes ausbequent to the administration of antibacterial agents. ent with antibacterial agents alters the normal flora of the colon and may permit who folgostrida. Studies indicate that a toxin produced by *Clostridium difficile* is a cause of "antibiotic-associated colitis."

overgrowth of clostridia. Studia's indicate that a toxin produced by *Clostridium difficile* is a primary cause of antibiotic-associated 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 (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more apt to occur in individuals with a history of penicillin typersensitivity and/or a history of sensitivity to multiple allergens. There have been well-documented reports of individuals with a history of penicillin hypersensitivity reactions who have experienced severe hypersensitivity reactions who have expenses hypersensitivity reactions and other altergens. If an allericy reaction succillin should be discontinued and the appropriate therapy instituted. SERIOUS ANAPTYLACTIC REACTIONS REDUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRIVE. OXYGEN, INTRAVENOUS STEROIDS, AUD AIRWAY MANAGEMENT, NCLUDING INTUBATIONS, SHOULD ALSO BE ADMINISTERED AS INDICATED. **PRECLATIONS**

Recourtons General Symptomatic response to therapy with lansoprazole does not preclude the presence of nastric mainancy

Jacure manyamus. 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 PLEWERD.

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

istration Options

aministration options 1. 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:

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

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:

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

juice (60 mL – approximately 2 ounces). • Mk 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. USE IN OTHER FOODS AND LIQUIDS HAS NOT BEEN STUDIED CLINICALLY AND IS THEREFORE NOT RECOMMENDED.

IHEREFURE NOT RECOMMENDED. 2. PREVACID Solurāb Delayed-Release Orally Disintegrating Tablets PREVACID Solurāb should not be cheved. 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, PREVACID Solurāb – per lowingen.

PREVACID SoluTab can be delivered in two different ways. PREVACID SoluTab – Oral Syringe For administration via oral syringe, PREVACID SoluTab can be administered as follows: • Place a 15 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. • Fellit the syringe with approximately 2 mL (5 mL for the 30 mg tablet) of water, shake gently, and administer any remaining contents.

EVACID SoluTab – Nasogastric Tube Administration (\geq 8 French) 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 to allow 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

3. PREVACID for Delaved-Release Oral Suspension

EVACID for Delayed-Release Oral Suspension should be administered as follows:

open packages to prepare a dose, empty the packet contents into a container containing 2 tablespoons of **VATER**. DO NOT USE OTHER LIQUIDS OR FOODS.

Str wen, and ornik 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 products should not be given through enteral administration tubes. Drug Interactions Lansoprazole is metabolized through the cytochrome P_{450} system, specifically through the CYP3A and CYP2C19 isozymes. Studies have shown that lansoprazole does not have clinically significant interactions with other drugs metabolized by the cytochrome P_{450} system, such as warfarin, antipyrine, indomethacin, ibuyrofen, phenytoin, propranolol, predinisone, diazepam, or clarithromytin in healthy subjects. These compounds are metabolized through various cytochrome P_{450} [sozymes including CYP1A2, CYP20, CYP2C19, CYP2D6, and CYP3A. When lansoprazole was administered concomitantly with theophylline (CYP1A2, CYP3A), a minor increase (10%) in the clearance of theophylline vas-seen. Because of the small magnitude and the direction of the effect on theophylline 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, and prothrombin time in patients receiving proton pump inhibitors, including lansoprazole, and prothrombin time in patients receiving proton pump inhibitors.

prothrombin time vere affected following single or multiple 60 mg doess of lansoprazole. However, there have been reports of increased International Normaized Ratio (INR) and varfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with proton pump inhibitors and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time. Lansoprazole has also been shown to have no cinically significant interaction with amoxicillin. In a single-dose crossover study examining lansoprazole 30 mg and omeprazole 20 mg each diministered alone and concomitantly with sucrafiate 1 gram, absorption of the proton pump inhibitors was delayed and their bioavailability was reduced by 17% and 16%, respectively, when administered concomitantly with sucrafiate. In clinical triats, antacids were administered and bind bio availability with sucrafiate. In clinical triats, antacids were administered concomitantly with PREVACID Delayed-Release Capsules; this did not interfere with its effect.

pump inhibitors was delayed and usen usavanaaming was resusce by the auto tow, respectively, when administered concomitantly with sucratate. In clinical traits, antacids were administered concomitantly with PsetVatto Delayed-Relase Capsules; this id 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 drugs where garinic pit is an important determinant of bioavailability (e.g., ketoconazole, ampiciallin esters, iron saits, digoxin). **Carcinogenesis, Mutagenessis, Impairment of Fertility** In two 24-month carcinogenicity studies, Sprague-Dawley rats were treated orally with doese of 5 to 50 mg/kg/day, 4bault 1 to 40 times the exposure on abody 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 (222 mg/m²). Lansoprazole produced does-related gastric enterochromaffin-like (ECI) cell hyperplasia and ECL cell carcinoids in both male and female rats. It also increased the incidence of these adenomas in rats receiving doese of 15 to 150 mg/kg/day (40 du times the recommended human dose based on body surface area) exceeded the low background incidence (range = 1.4 to 10%) for this strain of tar. Testicular interstitial cell adenoma as to 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 24-month carcinogenicity study. CD-1 mice were treated on body surface area, lasoprazole produced a lowe-related incidence of hose alor ob both cells in male mice treated on hork ackground incidence of a surface leaf on body surface area, lasoprazole an increased incidence of hose alor do budy surface area) in a diso produced a increased incidence of base alor ob doy surface area. Lasoprazole and increase incidence is male mice treated with 500 mg/kg/day (21 to 80 times the recommended human dose based on

aderration 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

Pregnancy Gargery B Lansoprazole (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

There are, however, no adequate or well-controlled studies in pregnant women. Because imart peroduction studies are not always predictive of human response, this drug should used during pregnancy only if clearly needed. regnancy Category C anthromycin ew WARNINGS (above) and full prescribing information for clarithromycin before using in more studies of the studies of the

e grant wome, ursing Mothers insoprazole or its metabolites are excreted in the milk of rats. It is not known whether nsoprazole is excreted in human milk. Because many drugs are excreted in human milk, cause of the potential for serious adverse reactions in nursing infantis from lansoprazole, id because of the potential for serious adverse reactions in nursing infantis from lansoprazole, dudes, a decision should be made whether to discontinue nursing or to discontinue using into account the importance of the drug to the mother. **Evalution Use** and effectiveness of PREVACID have been established in pediatric patients 1 to typars of age for short-term tratement of symptomatic GERD and erosive esophagilis. Use PREVADID in this population is supported by evidence from adequate and well-controlled usidaric patient is similar to that of adults. There were no adverse events profile in using indiatro patients is similar to that of adults. There were no adverse events profile in US inicial studies that were not previously observed in adults. The safety and effectiveness of REVADID in patients <1 year of age per bave not been established. **bit 1 years of age**

PhteVAULD III parents 5, 1997 The pediatric safety of PREVACID Delayed-Release Capsules has been assessed in 66 pediatric patients aged 1 to 11 years of age. Of the 66 patients with GERD 85% (56/66) 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=bo) Were consuperson (very -12 to 17 years of age The safety of PREVACID Delayed-Release Capsules has been assessed in these 87 adolescent patients. Of the 87 adolescent patients with GERD, 6% (5/87) to 600 PREVACID for 45 weeks, 92% (6/87) for 6 10 weeks, and 1% (1/87) for 51 Uweeks. The most frequently reported (at least 3%) treatment-related adverse events in these patients were headcher (7%), advoiding and (5%), nausea (3%), and dizziness (3%). Treatment-related dizziness, reported in this package insert as occurring in 1% of adult patients, were headcher (7%), duy by 3 adolescent patients with noncrosive GERD, who head divinese concurrently with other events (such as migraine, dyspnea, and vomiting).

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

Seen in maires. **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

Cilicial Working, over 10,000 patients have been treated with lansoprazole in Phase 2-3 clinical Working, over 10,000 patients have been treated with lansoprazole in Phase 2-3 clinical trials involving various dosages and durations of treatment. The adverse reaction profiles for PREVACID Delayed-Release Capsules and PREVACID for Delayed-Release Oral Suspension are similar. In general, lansoprazole treatment has been well-tolerated in both short-term and inong-term trials. The following adverse events were reported by the treating physician to have a possible or probable relationship to drug in 1% or more of PREVACID-treated patients and occurred at a greater rate in PREVACID-treated patients than placebo-treated patients. Incidence of Possibly or Probably

Incidence of Possibly or Probably Treatment-Related Adverse Events in Short-Term, Placebo-Controlled Studies		
	(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
Nausea	1.3	1.2

 Nausea
 1.3
 1.2

 leadache waa slos seen at greater than 1% incidence but was more common on placebo. The incidence of diarrhea was similar between patients who received placebo and patients who received lansoprazole 60 rg (2%, 4.7%, 4.2%, and 7.4%, respectively). The most commonly reported possibly or probably treatment-related adverse event during maintenance therapy was diarrhea.
 1.0

 In the risk reduction study of PREVACID for NSAID-associated gastric ulcers, the incidence of diarrhea tor patients treated with PREVACID was 5%, misoprostol 22%, and placebo 3%.
 3%, misoprostol 22%, and placebo 3%, diditional adverse experiences occurring in c1% or plateints or subjects in domestic trials re shown below. Refer to **Postmarketing** for adverse reactions occurring since the drug was marketed.

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. *Body as a Whole* – abdomen enlarged, allergic reaction, asthenia, back pain, candidiasis, carcinoma, chest pain (not otherwise specified), chills, edema, fever, flusyndrome, halitosis, infection (not otherwise specified), malaise, neck pain, neck rigidity, pain, pelvic pain; *Cardiovascular System* – angina, arritytmia, bradyacratia, cerebrovascular accident/cerebral infarction, hypertension/hypotension, migraine, myocardial infarction, palpitations, shoet (circulatory faultre), syncope, tach/ycardia, varebradia lucer, sophaglist, fecal discoloration, flatulene, gastric nodules/fundic gland polyps, gastritis, gastroenteritis, gastrointestinal discorder, gastrointestinal alsorie, gastrointestinal sorte, and thurtinoar *Jourgene en unable sorte*, between the sorte sorte and thurtinoard lucerative, nausea and vomiting, and darrate, oral monilasis, rectal disorder, rectal hemorrhage, stomatitis, tenesmus, thirst, tongue disorder, lucerative colits, *Jourgene 20*, delydration, hyperdyceniard/proglycemia, peripheral edema, weight gainloss: *Musculoskeletal System* - athralgia, arthritis, bone disorder, joint disorder, leg parames, musculoskeletal System - athralgia, arthritis, bone disorder, joint disorder, leg parames, musculoskeletal System - athralgia, arthritis, bone disorder, peripheral edema, weight garands, hyperkinesia, hypertonia, hypesthesia, insomia, libdio decreased, dyspuea, epistaxis, hemotysis, paresthesia, subethis, ansomia, libdio decreased, dyspuea, epistaxis, hemotysis, paresthesia, solardit, rough increased, dyspuea, epistaxis, hemotysis, targenent, breast pain, breast theof

Pestimarketing Or-going Safety 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 trequency cannot be made. These events are listed below by COSTART body system. hepatotoxicity, pancrastits, and a Whole - anaphylactoid-like reaction; *Digestive System* - hepatotoxicity, pancrastits, anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, and thrombotic inrombocytopenio purpura; *Skin and Agenotages* - severe dermalobigic reactions including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (some fata); *Special Senses* - speech disorder, *Urgenital System* - urinary retention. Combination Therapy with Amoxicillin and Clarithromycin In clinical trials using combination therapy with PREVACID plus amoxicilin and clarithromycin, and PFEVADID bus amoxicilin, no adverse reactions peculiar to these drug combinations were observed. Adverse reactions that have occurred have been limited to those that hab been previously reported with PREVACID, amoxicilin or clarithromycin. Tripit Direapy: PREVACID/amoxicillin/clarithromycin the most frequently reported averse events for patients who received triple therapy for 14 days were diarrhea (7%), headache (6%), and taste perversion (5%). There were no observed a tsignificant differences in the frequency of reported averse events between the 10- and 14-day tripit herapy regimens. No treatment-mergent adverse events to observed a tsignificantly hiptor taste with triple therapy than with any dual therapy regimen. Dual Therapy: PREVACID/amoxicillin

observed at significantly inginer rates with inple therapy man with any dual therapy regimen. Dual Therapy, PENADID/amoci/cillini The most frequently reported adverse events for patients who received PREVACID Li.d. plus amoxicillin Li.d. dual therapy were diarrhea (8%) and headache (7%). No treatment-emergent adverse events were observed at significantly higher rates with PREVACID Li.d. plus amoxicillin Li.d. dual therapy than with PREVACID alone. For more information on adverse reactions with amoxicillin or clarithromycin, refer to their package inserts, **ADVERSE REACTIONS** sections.

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

events: Abnormal liver function tests, increased SGOT (AST), increased SGPT (AIT), increased Abnormal liver function tests, increased solutions, increased GGTF increased/decreased/abnormal MBC, abnormal AG ratio, abnormal ABC, billirubinemia eosinophilla, hyperlipenia, increased/decreased electrolytes, increased/decreased/ cholesterol, increased guocoorticoids, increased LDH, increased/decreased/abnormal hyperlatelts, and increased gastrol evels. Unite abnormalities such as abuminuria, glycosuria and hematuria were also reported. Additional isolated laboratory abnormalities were reported

The instantial rate also reported. Automate Isolated abortatory automatics were reported. In the placebo controlled studies, when SGOT (AST) and SGPT (ALT) were evaluated, 0.4% (4/376) 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 jauncioe at any time during the study. In clinical trials using combination therapy with PREVACID plus amoxicillin and clarithomycin, 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. to their package inserts, **ADVERSE REACTIONS** Section. **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) and mice (about 675.7 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) and mice (about 675.7 times the recommended human dose based on body surface area) Entropy the dot mice inclusion the circulation by hemodalysis. In one reported case of overdose, the patient consumed 600 mg of lansporale with no adverse reaction. Distributed by Tar Pharmaceutical sinc. Lake Forest, IL 60045, U.S.A. ENSURF® is a registred trademark of Abbott Laboratories. Ref. 02-5366-R24 Rev. July. 2004 © 1995-2004 TAP Pharmaceutical Products Inc. For more detailed information, see full prescribing information or contact TAP Medical Information at 1-800-622-2011. MB030-0134