

INDICATIONS AND USAGE

Treatment of Gastroesophageal Reflux Disease Associated With a History of Erosive Esophagitin

Short-term treatment (7 to 10 days) of patients having postineacohapsell reflux disease (GHD) with a history of entire ascophapita, as an alternative to oral therapy in patients who are smalle to continue taking PROTONIX (pantoprazule sodium) Delayed-Release Tablets. Selecy and efficacy of PROTONIX I/or Injection as an initial insurrent of patients haven 5550 units. In the patients of the patien

Pathological Hypersecretion Associated With Zollinger-Ellison Syndrome

Treatment of pathological hypersecretory conditions associated with Zollinger-Ellison syndrome or other neopiastic conditions.

CONTRAINDICATIONS

PRECAUTIONS

truned-alle hypersensitivity reactions: Anaphylaus has been reported with use of sitravenous pantispracele. This may require emergency medical treatment. injection site reactions. Thrombophlebits was associated with the administration of intravenous pantoprarole

Hegatic effects: Mild, transent transamouse elevations have been observed in clinical studies. The clinical agenticance of this finding in a large population of aubjects administered intravenus participazole is unknown. (See ADVERSE BEACTIONS section.)

Symptomic response to terapy with perimprasse dis unacount, lose a puternot executive adiquancy.

Symptomic response to therapy with perimprasse does not preclude the presence of gastric malignancy.

As with any other instanceus product containing electate discolutin (the salf form of EDTA) which is a potent chelator of metal ions including zinc, and supplementation should be considered in patients bested with PROTONIX.LV for Injection who are poore to zinc deficiency. Caution should be used when other supplementation should be considered in patients bested with PROTONIX.LV for Injection who are poore to zinc deficiency. Caution should be used when other EDTA containing products are also co-administrated intraversably.

Treatment with PROTONIX IV. for trijection should be discontinued as soon as the patient is able to resume treatment with PROTONIX Delayed-Release Tablets.

Drug Interactions
Pursporate is relatables emainly by CYP2C19 and to musor extents by CYPs 344, 206, and 209 in in who drug drug interaction studies with CYP2C19 substrates incurrence and primary in the control of th

Lacrinogenesis, Nutagenesis, Intragenesis, International I Sporadic occurrences of hepatocellular adenomes and a hepatocellular carcinoma were observed in Sprague-Dawley rats exposed to pantoprazole in 6-month and

12-month craft toxicity studies.

In a 24-month carcinogenicity study, Fischer 344 rats were treated orally with doses of 5 to 50 mg/kg/day, approximately 1 to 10 times the recommended fruman dose based no body surface area. In the gestire fundics, treatment at 5 to 50 mg/kg/day produced entercorbornalifin like (ECL) cell hyperplassa and benign and malignant neuroscriborinic cell funors. Dose selection for this study may not have been adequate to comprehensively evaluate the coincogenicity study, 805-31 mice were bested orally with doses of 5 to 150 mg/kg/day 0,5 to 15 times the recommended fruman dose based on the colon orall control orally with doses of 5 to 150 mg/kg/day 0,5 to 15 times the recommended fruman dose based on the colon orall control orally orall

at 3 to 150 ingragrany also processes gather future ELL of impropasas.

Participation was positive in the in strot human lymphocytic informational aberration assays, in one of two mouse micronucleus tests for cleatogamic effects, and in the in vitro Tests humans contribited. The process are also shall were observed in the in vivo rat liver DNA condent binding assay. Participation was regarder in the in vitro Ames mutation assay, the in vitro unscheduled DNA symbols (IUS) assay with rat hepathoples, the in vitro Ames mutation assay, the involved the process of the proces

Participation at creat doses up to 500 mg/kg/day in male rats (88 times the recommended human dose based on body surface area) and 450 mg/kg/day in famile rats (88 times the recommended human dose based on body surface area) and 450 mg/kg/day in famile rats 88 times the recommended human dose based on body surface area) was found to have no effect on fartifity and reproductive performance.

Pregnancy Category B

Tendatory studies have been performed in rats at intravenous disces up to 20 mg/kg/day (4 times the recommended human dose based on body surface areal and reachbits at intravenous disces up to 15 mg/kg/day (5 times the recommended human dose based on body surface areal and have revealed no evidence of impaired fertility or harm to the letus due to pentipracele. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used thiring pregnancy only if clearly needed.

Participazate and its metabolites are excreted to the milk of rats. Participazate excretion in human milk has been detected in a study of a single musting mother after a single 40 mg oral dose. The clinical relevance of this finding is not known. Many drugs which are excreted in human milk have a potential for serious adverse reactions in musting infants. Based on the potential for human genicity shown for personance in robert carcinogenicity studies, a decision should be made whether to decorations nursing of to discontinue the drug, taking into account the benefit of the drug to the mother.

No gender-related differences in the safety profile of intravences pantoprazole were seen in internetional trials involving 166 men and 120 woman with enaith rise genore reaction controlled in the period provide in enterpretation of the period of the period

No agreement of the more in the safety profile of introvenous participants were seen in international trials involving 86 elderly iz 65 years old) and 200 younger Iz 65 years old patients with enough enoughputs associated with ERRIC trials escoplaging basing rates in the 107 elderly patients (2 65 years old) heated with oall patients with enough enoughput enoughput and in the 107 elderly patients (2 65 years old) heated with oall patients and its patients and water the age of 67. The incidence rates of odverne events and laboratory abnormalities in patients age of years and older were similar to those associated with patients younger than 65 years of age.

There have been reports of folioe-goodine unine screening tests for tetrahydrocamabinal (THC) in patients receiving most proton pump inhibitors, including

Safety Experience With Intravenous Pantoprazole

Intravenous partoprazile has been studied in clinical trials in several populations including parients having GERD with a history of ensive exophagitis, patients with Zollinger-Elisans syndrome, and healthy subjects. Adveter experiences occurring in 51% of patients treated with intravenous partoprazible (n=714) in domestic and international clinical trials are shown below by body system. In most instances, the relationship to partoprazible was unclear.

BODY AS A WHOLE abdominal pain, headache, injection site reaction (including thrombophlebitis and abscess).

DIGESTIVE SYSTEM: constigation, dyspepsia, nausea, dianthea.

NERVOUS SYSTEM: insormia.

The date deed comparative studies between PROTONX I.V for Injection and onli PROTONX, other proton pump inhibitors foral or I.V.L or HZ receptor anappoints foral or I.V.L have been initiated. The available information does not provide sufficient evidence to distinguish the safety profile of these regimens.

Safety Experience With Oral Pantoprazole in short-term clinical trials in patients with erosive ecophagitis associated with GEPD treated with and participazole, the following adverse events, regardless or

BODY AS A WHOLE: headache, asthenia, back pain, chest pain, neck pain, flu syndrome, infection, pain.

CARDIOVASCULAR SYSTEM: migraine.

DIGESTIVE SYSTEM: diarrites, flatulence, abdominal pain, excitation, constigation, dyspepsia, gastroententis, gastrointestinal disorder, valuese, rectal disorder, vomiting,

HEPATO-BILLIARY SYSTEM: liver function tests abnormal, SGPT increases

METABOLIC AND NUTRITIONAL hyperglycemia, hyperlipemia

MUSCULOSKELETAL SYSTEM, arthrolgia

RESPRATORY SYSTEM: brunchitis, cough increased, dysprea, pharyogitis, minitis, sinustits, suppr respiratory tract effection

UROGENITAL SYSTEM: urinary frequency, urinary tract infect

UNDUCKING OF SIZES. SHAPE INTERPRETATION OF A STATE OF BODY AS A WHOLE abscess, allergic reaction, chills, cyst, face edema, fever, generalized edema, heat stroke, hernia, laboratory test abnormal, melaise, monitiess,

neoposin, narspectives usg research.

CADIOVASCULAR SYSTEM: abnormal electrocardiogram, argina pectors, arthythma, cardiovascular disorder, chest pain substarral, congestive heart failure.
hemorrhage, hypertansion, hypotherision, myocardial ischemia, palpitation, retinal vascular disorder, syncope, tachycardia, thrombophiebitis, thrombosis,

DIGESTIVE SYSTEM: anorexia, aphthous stomatria, cardisopasm, coloris, dry mouth, duodenitis, dysphagia, enteritis, esophagiai hemorrhage, esophagiais, pastrointestrial carcinoma, pastrointestrial hemorrhage, gastrointestrial monitasis, proprintir, plosotis, hallitois, hematemasis, noreased apportint, melena, nouth udersation, yral monitasis, periodontal abscess, periodontals abscess, periodontals abscess, periodontals abscess, periodontals, rectal hemorrhage, stomach ulcer, stomatris, stools absormal, tongue discoloration, ulcerative

HEPATO-BILARY SYSTEM bilary pair, hyperbili-binemia, cholecystiss, cholestake, cholestake, jeundice, hepatitis, alkaline phospistate increased, gamma glutamyl transperidate increased, SSOT increased.

HEMIC AND LYMPHATIC SYSTEM; anemia, exchymosis, eosinophilia, hypochromic anemia, iron deficiency anemia, leukocytosis, leukocyenia, thronbocytopenia METABOLIC AND NUTRITIONAL dehydration, edema, gout, peripheral edema, thirst, weight gain, weight loss.

MUSCULOSKILETAL SYSTEM arthrifs, anthrosis, bone disorder, bone pain, barstiss, part disorder, leg cramps, neck rigidin, myalga, tenceprioris.

NERVILIS SYSTEM absormal deams, confusion, consultation, depression, dry modif, dysarthris, emotional lability, hallucinations, hyperkness, hyperkness, hyperkness, hyperkness, indicated, nervicioness, neuraliga, neurifici, parestress, reflexes decreased, sleep disorder, somnolence, thinking abnormal, tramp, vertigu. RESPIRATORY SYSTEM: asthma, epistaxis, hiccop, laryngitis, lung disorder, poleumonia, voice alteration.

SCN AND APPENDAGES acres alopecia, posted demastria, dry sion, eczona, lungal demastria, hemontrage, herpes singlex, herpes zostar, lichenold demastria, macinospoliar rath, pain, grunius, sion disorder, sim ulcer, sweating, unicaria:

SPECIAL SENSES: abnormal vision, amplyopia, catacast specified, deafness, diplopia, ear pain, extraocular pulsy, plancoma, orbits externa, taste perversion, firmition OF CASH A STATE OF BRANCH STATEM, STAT

The polaritations are portained in a production of the secret with a polaritation of the secret and the secret polaritation of th

In U.S. clinical trials of patients having GERD with a history of erosive exphagins and international clinical trials of patients with encive exchagins associated with GERD, the overall percentages of transaminase elevations old not increase during treatment with intravenous participations. For other laboratory parameters, there were no clinically important charges identified.

are nepatically imparted.

Because of profound and long latting inhibition of gastric acid secretion, partopsable may interfere with absorption of drugs where gastric pH is an important.

The horse of profound and long latting inhibition of gastric acid secretion, partopsable may interfere with absorption of drugs where gastric pH is an important of their boxysiability legs, intercontable, amplified setters, and row salts.

Carcinogenesis, Martagenesis, Impairment of Ferfity

In a 24-north exception secretic partopsable may be used to be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carcinet secretic partopsable may be mild and sponder.

The following changes in abouting changes in aboutiny carcinet secretic partopsable may be mild and sponder. The following changes in aboutiny carci

Single intravenous dozes of participatorie at 378, 238, and 268 mg/kg (35, 46, and 177 times the recommended human doze based on body surface area) were letter to mice, rata, and doze, respectively. The symptoms of acute toxicity were hypoactivity, staxia, hunched sitting, limb-splay, lateral position, segregation.

DOSAGE AND ADMINISTRATION

PROTONIX. I.V. for Injection may be administered intravenously through a dedicated line or through a Y-site. The intravenous line should be flushed before and after administration of PROTONIX. IV. for Injection with either S% Discrete Injection, USP 0.9% Sodium Discrete Injection, USP or Lacasted Ringer's Injection, USP when administrated through a Y-site, PROTONIX IV. for Injection is compatible with the following solutions: 5% Destrose Injection, USP, 0.9% Sodium Discrete Injection, USP, or Lacasted Ringer's Injection, USP.

Middacelem HCI has been shown to be incompatible with Y-site administration of PROTONXX.V. for injection. PROTONXX.V. for injection may not be compatible with products containing znr. When PROTONXX.V. for injection is administered through a Y-site, immediately stop use if precipitation or discolaration occurs.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to and during administration whenever solution and container permittens and discoloration prior to and during administration whenever solution and container permittens and discoloration prior to and during administration whenever solution and container permittens. Treatment with PROTONIX IV for injection should be discontinued as soon as the patient is able to resume treatment with PROTONIX Delayed-Release Tuber Also, data on the safe and effective disorg for conditions other than those described in INDICATIONS AND USAGE, such as life threatening upper patriorization bleeds, are not weilable PROTONIX IV 40 mg once daily does not raise gastric pit to levels sufficient to contribute to the treatment of such life-threatening conditions. Parentural routes of administration other than intravenous are not recommended.

No dosage adjustment is necessary in patients with renal impairment, hepatic impairment, or for elderly patients. Doses higher than 40 mg/day have not been musted in hepatically-impaired patients. No dosage adjustment is necessary in patients undergoing hemodialities.

Treatment of Gastroesophageal Reflux Disease Associated With a History of Erosive Esophagitis

The recommended abult dose, as an alternative to continued oral therapy, is 40-mg participated given once daily by intravenous influsion for 7 to 10 days. Safety and efficacy of PROTONIX LV for injection as a treatment of patients having GERO with a history of erestive esophaghts for more than 10 days have not been demonstrated (see INDICATIONS AND USAGE).

PROCION I.V. for Injection should be reconstituted with 10 ml, of 0.9%. Sodium Otherde Injection, USP, and further diluted (admixed) with 100 ml, of 5% Derivine Injection, USP, 0.9%. Sodium Otherde Injection, USP, or a final concentration of approximately 0.4 mg/ml. The reconstructed bioget's Injection, USP, or a final concentration of approximately 0.4 mg/ml. The reconstructed solution may be stored for up to 72 hours at noon temperature prior to further dilution; the admixed solution may be stored for up to 72 hours at noon temperature prior to intravenous inflation. Both the reconstituted solution and the admixed solution so not need to be proticted from light.

PROTONIX LV, for Injection administures should be administured intravenously over a period of approximately 15 minutes at a rate of approximately 7 mL/min

Two Minute Infusion

PROTONIX TV. for injection should be reconstituted with 10 ml, of 0.9% Sodium Chloride Injection, USP, to a final concentration of approximately 4 mg/lml. The reconstituted solution may be stated for up to 2 hours at noon rereperature prior to intravenous influsion and does not need to be protected from fight. PROTONIX TV. for injection should be administered intravenously over a period of at least 2 minutes.

Pathological Hypersecretion Associated With Zollinger-Ellison Syndrome

The dosage of PROFONX IX for injection in patients with pathological hypersecretory conditions associated with Zollinger-Ellion syndrome or other necelastic conditions were with individual patients. The recommended adult dosage is 80 mg of 2%. The frequency of doring can be adjusted to individual patient needs based on acid output measurements. In those patients who need a higher dosage, 80 mg ofth is expected to maintain acid output below 10 might. Daily dozes they have not 240 mg or administred for more than 6 days have not been studied. (See Clinical Studies section of full Prescribing informations of restriction from road to 12 and from IX to ori informations of agant or add inhibitors should be performed in such a mainter to ensure continuity of effect of suppression of acid secretion. Patients with Zollinger-Ellison syndrome may be volverable to serious clinical complications of increased acid production even after a short period of loss of effective exhibition.

Each val of PROTONIX IV for injection should be reconstituted with 10 mt. of 0.9% Sodium Chloride Injection, USP. The contents of the two valis should be combined and further differed statement with 60 mt. of 5% Destrose Injection, USP 6.9% Sodium Chloride Injection, USP, or lactated Ringer's Injection, USP, to a total volume of 10 mt. with a final consentration of approximately 0.5 mg/mt. The reconstituted solution may be stored for up to 2 hours at room temperature prior to intrinsicialistic, the administration of approximately 2.5 mg/mt. The reconstituted solution may be stored for up to 2.2 hours at room temperature prior to intrinsection. Both the reconstituted solution and the administration of the solution of out reset to be protocled from light.

FROTONIX.LV. for Injection should be administered intravenously over a period of approximately 15 minutes at a rate of approximately 7 mL/min

POTIONX IV. for injection should be reconstituted with 10 mL of 0.9% Sodium Chloride Injection, USP, per visit to a final concentration of approximate angles. The reconstituted solution may be stored for up to 2 hours at noon temperature prior to intraversions influsion and does not need to be protected from The total volume from both valus should be administered intravenously over a period of at least 2 minutes.

US Patent No. 4,758.579

Wyeth[®]

078467 Konstanz, Germany

This Brief Summary is based on the approved PROTONIX I.V. for Injection direction circular W10447C008 ET01, revised 04/04

DIAGNOSIS AT A GLANCE

By Brian R. Irwin, DO, Kerry A. Peters, MD, and Alan Jon Smally, MD, FACEP



Case submitted by Dr. Irwin

CASE I

A five-year-old Bolivian boy is evaluated during an international medical clinic in his rural village. He, like all his fellow villagers, has never seen a physician before. Since birth, he has been experiencing recurrent, lingering respiratory infections, sometimes featuring a productive cough with foulsmelling sputum. He and other family members have recently had scabies and are at risk for parasitic infections, which run rampant in this locale. Physical examination reveals no rash, with the exception of a punctate lesion near the sternal notch that exudes purulent material when expressed. The only other abnormalities are cervical adenopathy and a soft, subtle mass lateral to the patient's cricoid that is mobile and moves with swallowing. The boy's oropharynx, lungs, and nose are unremarkable.

What is your diagnosis?



Case submitted by Drs. Peters and Smally

CASE 2

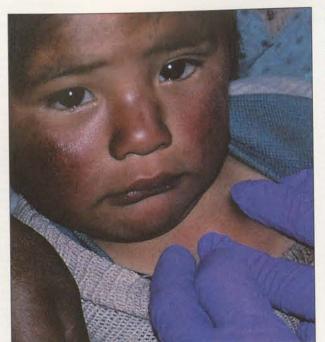
A 32-year-old man presents to the emergency department with a clinically apparent fracture of his left wrist. He is in moderate to severe pain. The nurse places an intravenous (IV) catheter in his right antecubital area and administers 5 mg of morphine by IV push. Shortly thereafter the patient develops itching above the catheter and the rash shown at left, along with a very mild generalized pruritus. The attending physician is asked if epinephrine, antihistamines, and corticosteroids are indicated

What is your diagnosis?

Turn page for answers

www.emedmag.com

JUNE 2004 EMERGENCY MEDICINE 29



CASE I

This patient had a thyroglossal duct cyst and sinus. The limited resources of a goodwill clinic in a remote location precluded any testing, but with a punctate skin lesion a parasitic or worm infection was also likely, so he was treated with anthelmintics in addition to a broad-spectrum antibiotic. He was brought to a surgeon in La Paz who incised the fluctuant mass and discovered a sinus tract running from the sternal notch to the underside of the boy's tongue, which had been missed in the initial examination. Thyroglossal cysts result from the failure of the first, second, and sometimes third and fourth branchial clefts to fuse during the first two months of embryonic development. Most cysts are infected with mixed flora or gram-positive organisms. Occasionally, tracts connect to the oropharynx, where aspiration of material can lead to respiratory infection.



CASE 2

The photo demonstrates an itchy, dendritic reaction that developed along the course of a vein shortly after the injection of morphine. Although it may be confused with an allergy, this is actually a pseudoallergy because it does not involve the release of IgE and is distinguished by the predominance of local findings without systemic manifestations such as nausea, vomiting, hypotension, or angioedema. It is more likely to occur when larger amounts of morphine are given more rapidly. Recognizing this presentation as a nonallergic cutaneous reaction permits symptomatic treatment, avoids unnecessary or potentially dangerous interventions, and allows further use of morphine (or other narcotics). Treatment is with reassurance, cool compresses, and systemic antihistamines. These reactions may be prevented by slower administration of a more dilute morphine solution or by the use of an analgesic that does not cause histamine release, such as fentanyl.

Dr. Irwin is a physician in private practice at Saco River Medical Group in Conway, New Hampshire. Dr. Peters is an attending physician at Cape Cod Hospital in Hyannis, Massachusetts. Dr. Smally is an associate professor in the department of traumatology and emergency medicine at Hartford Hospital and the University of Connecticut School of Medicine in Hartford.

First-Line Response

Empiric therapy for complicated intra-abdominal and skin/skin structure infections





Demonstrated gram-positive, gram-negative. and anaerobic coverage

V QD monotherapy

INVANZ is indicated for the treatment of adult patients with moderate to severe:

Complicated intra-abdominal infections due to Escherichia coli, Clostridium clostridioforme, Eubacterium lentum, Peptostreptococcus species, Bacteroides fragilis, B distasonis, B ovatus, B thetaiotaomicron, or B uniformis.

Complicated skin/skin structure infections due to Staphylococcus aureus (methicillin-susceptible strains only), Streptococcus pyogenes, Escherichia coli, or Peptostreptococcus species.

Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to INVANZ. Therapy with INVANZ may be initiated empirically before results of these tests are known; once results become available, antimicrobial therapy should be adjusted accordingly.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of INVANZ and other antibacterial drugs. INVANZ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

INVANZ is contraindicated in patients with known hypersensitivity to any component of this product or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to beta-lactams.

Due to the use of lidocaine HCl as a diluent, INVANZ administered intramuscularly is contraindicated in patients with a known hypersensitivity to local anesthetics of the amide type. (Refer to the prescribing information for lidocaine HCL)

Seizures and other CNS adverse experiences have been reported during treatment with INVANZ.

During clinical trials, the most common drug-related adverse experiences in patients treated with INVANZ, including those who were switched to therapy with an oral antimicrobial, were diarrhea (5.5%), infused vein complication (3.7%), nausea (3.1%), headache (2.2%), vaginitis in females (2.1%), phlebitis/thrombophlebitis (1.3%), and vomiting (1.1%).

Before prescribing INVANZ, please read the Brief Summary of the Prescribing Information on the adjacent page.

INVANZ is a registered trademark of Merck & Co., Inc.



invanz.com © 2004 Merck & Co., Inc. All rights reserved. 20404652(2)(002)-INV