Esmatac capsule

Esmatac: Esmatac 20 mg capsule, Esmatac 40 mg capsule.:
Generic Name: Esomeprazole magnesium.
Pharmaceutical forms: Capsules.
Therapeutic Indications:
Treatment of gastroesophageal reflux diseases (GERD):
Healing of Erosive Esophagitis.
Esmatac is indicated for the short term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis.
For those patients who have not healed after 4 to 8 weeks of treatment, an additional 4 to 8 weeks course of Esmatac may be considered.
Maintenance of Healing Erosive Esophagitis: Esmatac is indicated to maintain symptom resolution and healing erosive esophagitis.Controlled studies do not extend beyond 6 months.
Symptomatic Gastro esophageal reflux disease: Esmatac is indicated for short term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults and children 1 years or older.
Risk reduction of NAISD-Associated Gastric Ulcers: Esmatac is indicated for the reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in patients at risk for developing gastric ulcers. Patients are considered to be at risk due to their age (≥ 60) and/or documented history of gastric ulcers. Controlled studies do not extend beyond 6 months.
H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence:
Triple Therapy (Esmatac Plus amoxicillin and Clarithromycin): Esomeprazole, in combination with amoxicillin and clarithromycin, is indicated for the treatment of patients with H.Pylori infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate H. Pylori. Eradication of H. Pylori has been shown to reduce the risk of duodenal ulcer recurrence.
In patients who fail therapy, susceptibility testing should be done.
If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.
Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome :
Esmatac is indicated for long term treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome.
Patients requiring continued NSAID Therapy:
- Healing of gastric ulcers associated with NSAID therapy.
- Prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk.

Posology and method of administration:
The capsules should be swallowed whole with liquid and must not be chewed or crushed.
For patients who cannot swallow, the capsules can be opened in non- carbonated water.
Gastroesophageal Reflux Diseases (GERD):
- Treatment of erosive reflux esophagitis: 40 mg daily for 4 weeks. An Additional 4 weeks treatment is recommended for patients in whom esophagitis has not healed or who have persistent symptoms.
- Long term management of patients with healed esophagitis to prevent relapse: 20 mg once daily.
- Symptomatic treatment of gastro esophageal reflux disease (GERD): 20 mg once daily in patients without esophagitis. If symptoms control has been achieved after 4 weeks the patients should be further investigated. Once symptoms have resolved, subsequent symptom control can be achieved using 20 mg once daily. In adults, an on demand regimen taking 20 mg once daily, when needed can be used.
- In NSAID treatment patient at risk of developing gastric and duodenal ulcers, subsequent symptoms control using an on demand regimen is not recommended.

In combination with an appropriate antibacterial therapeutic regimen for eradication of Helicobacter pylori:
- Healing of Helicobacter pylori associated duodenal ulcers
- prevention of relapse of peptic ulcers in patients with Helicobacter pylori associated ulcers

20mg Esmatac with 1 g amoxicillin and 500 mg Clarithromycin, all twice daily for 7 days.
Patients requiring continued NSAID Therapy:
- Healing of gastric ulcers associated with NSAID therapy: the usual dose is 20 mg once daily. the Treatment duration is 4 – 8 weeks.
- Prevention of gastric and duodenal ulcers associated with NSAID therapy is patient at risk : 20 mg once daily.

Treatment of Zollinger Ellison Syndrome: The recommended initial dosage is Esmatac 40 mg twice daily, the dosage should then be individually adjusted and treatment continued as long as clinically indicated. Based on clinical data available, the majority of a patient can be controlled on doses between 80 – 160 mg esomeprazole daily. With doses above 80 mg daily the doses should be divided and given twice daily.
Children below the age of 12 years: Esmatac should not be used in children younger than 12 years since no data is available.
Impaired renal function: Dose adjustment is not required in patients with impaired renal function. Due to limited experience in patients with severe renal insufficiency, such patients should be treated with caution.
Impaired Hepatic function: Dose adjustment is not required in patients with mild to moderate liver impairment. For patients with severe liver impairment, a maximum dose of 20 mg esomeprazole should not be exceeded.
Elderly : Dose adjustment is not required in the elderly.
Contraindications:
- Known hypersensitivity to esomeprazole, substituted benzimidazoles or any other constituents of the formulation.
- Esmatac like other PPIs should not be administrated with atazanvir.

Special warning and special precaution for use:
• ***Current Gastric Malignancy:*** Symptomatic response to therapy with esomeprazole does not preclude the presence of gastric malignancy.
• ***Atrophic Gastritis:*** Atrophic Gastritis has been noted occasionally in gastric corpus biopsies from patient treated long term with omeprazole of which esomeprazole is an enantiomer.
• ***Risks of Amoxicillin (as Part of H. pylori Triple Therapy):***
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions has been reported in patients on penicillin therapy. These reactions are more apt to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens .
There have been well documented reports of individuals with a history of penicillin hypersensitivity reactions that have experienced serve hypersensitivity treated with cephalosporin. Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillin, cephalosporin and other allergens. If an allergic reaction occurs amoxicillin should be discontinued and the appropriate therapy instituted.
Serious anaphylactic reactions require immediate emergency treatment epinephrine, oxygen, intravenous steroids and airway management, including intubation, should also be administrated as indicated.
Pseudomembranous colitis has been reported with nearly all antibacterial agents, including clarithromycim and amoxicillin, and may range of severity from mild to life threatening.
Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.
Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth Clostridia. Studies indicate that a toxin produced by Clostridium difficile is primary cause of "antibiotic-associated colitis".
After diagnosis of pseudodomembranous 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, proteins supplementation and treatment with an antibacterial drug clinically effective against clostridium difficile colitis
• ***Risks of Clarithromycin (as Part of H. pylori Triple Therapy):***
Clarithromycin should not be used in pregnant women except in clinical circumstances where no alternative therapy is appropriate. If pregnancy occur while taking clarithromycin, the patient should be apprised of the potential hazard to the fetus.
Concomitant administration of clarithromycin with cisapride, pimozide, astemizole, terfenadine, ergotamine or dihydroergotamine is contraindicated.
• Prescription proton pump inhibitor (PPI) drugs may cause low serum magnesium levels (hypomagnesemia) if taken for prolonged periods of time (in most cases, longer than one year), magnesium supplementation alone did not improve low serum magnesium levels and the PPI had to be discontinued.
• Low serum magnesium levels can result in serious adverse events including muscle spasm (tetany), irregular heartburn (arrhythmias), and convulsions (seizures); however, patients do not always have these symptoms. Treatments of hypomagnesemia generally requires magnesium supplements. Treatment in patients taking a PPI and who have hypomagnesemia may also require stopping the PPI.
• ***Bone Fracture:***
"Several published observational studies suggest that proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis- related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis- related fractures should be managed according to the established treatment guidelines".
Interactions:Effects of esomeprazole on the pharmacokinetics of other drugs.
Medicinal products with PH dependent absorption:
The decreased intragastric acidity during treatment with esomeprazole, might decrease or increase the absorption of drugs if the mechanism of absorption is influenced by gastric acidity.
In common with the use of other inhibitors of acid secretion or antacids, the absorption of ketoconazole and itraconazole can decrease during treatment with esomeprazole.
Co-administration of omeprazole (40 mg once daily) with atazanfir 300 mg / ritonavir 100 mg to healthy volunteers resulted in a substantial reduction of atazanvir exposure (approximately 75 % decrease in AUC, Cmax, Cmin).
Increasing atazanvir to 400 mg did not compensate for the impact of omeprazole on atazanvir exposure .
PPIs including esomeprazole should not be Co-administrated with atazanvir.
Drug metabolized by CYP 2C19:
Omeprazole acts as inhibitor of CYP2C19. Omeprazole given in doses 40 mg daily for one week to 20 healthy subjects in cross-over study, increased Cmax and AUC of cilostazol by 18 % and 26% respectively. Cmax and AUC of one of its active metabolite, 3,4 dihydrocilostazol, which has 4 – 7 times the activity of cilostazol, were increased by 29% and 69% respectively.
Co-administration of cilostazol with esomeprazole is expected to increase concentration of cilostazol and its above mentioned active metabolite. Therefore a dose reduction of cilostazol from 100 mg b.i.d. to 50 mg b.i.d. should be considered .
Esomeprazole inhibits CYP2C19 the major esomeprazole metabolizing enzyme. Thus, when esomeprazole is combined with drugs metabolized CYP2C19 such as diazepam, Citalopram, imipramine, clomipramine, phynetoin etc. the plasma concentration of these drugs may be increased and a dose reduction could be needed. This should be considered especially when prescribing esomeprazole for on demand therapy .
Concomitant administration of 30 mg esomeprazole resulted in 45 % decreased in clearance of the CYP2C19 substrate diazepam. Concomitant administration of 40 mg esomeprazole resulted in 13 % increase in trough plasma levels of phenytoin in epileptic patients. It is recommended to monitor the plasma concentrations of phenytoin when treatment with esomeprazple is introduced or withdrawn. Omeprazole (40 mg once daily) increased voriconazole (a CYP2C19 substrate) Cmax and AUC by 15 % and 41 % respectively.
Concomitant administration of 40 mg of esomeprazole to warfarin treated patients in clinical trial showed that coagulation times were within the accepted range.
However post-marketing, a few isolated cases of elevated INR of clinical significance have been reported during concomitant treatment. Monitoring is recommended when initiating and ending concomitant esomeprazole treatment during treatment with warfarin or other coumarine derivatives.
In healthy volunteers concomitant administration of 40 mg esomeprazole resulted in a 32 % increase in area under the plasma concentration time curve AUC and a 31% prolongation of elimination half life (t 1/2) but no significant increase in peak plasma levels of cisapride. The slight prolonged QT_C interval observed after administration of cisapride alone, was not further prolonged when cisapride was given in combination with esomeprazole.
Esomeprazole has been shown to have no clinically relevant effects on pharmacokinetics of amoxicillin or quinidine. Studies evaluating concomitant administration of esomeprazole and either naproxen or rofecoxib did not identify any clinically relevant pharmacokinetic interactions during short-term studies.
Effects of other drugs on the pharmacokinetics of esomeprazole
Esomeprazole is metabolized by CYP2C19and CYP3A4. Concomitant administration of esomeprazole and CYP3A4 inhibitor, clarithromycin (500mg b.i.d.), resulted in doubling of exposure (AUC) esomeprazole.
Dose adjustment of esomeprazole is not required
Pregnancy and lactation:
For Esomeprazole, clinical data on exposed pregnancies are insufficient. With the racemic mixture omeprazole data on a large number of exposed pregnancies from epidemiological studies indicate no malformative nor foetotoxic effects.
Animal studies with esomeprazole do not indicate direct or indirect harmful effects with respect to embryonal / fetal development.
Animal studies with the racemic mixture do not indicate direct or indirect harmful effects with respect to pregnancy parturition or postnatal development.
Caution should be exercised when prescribing to pregnant women
It is not known whether esomeprazole is excreted in human breast milk. No studies in lactating women have been performed. Therefore esomeprazole should not be used during breast-feeding
Effects on ability to drive and use machines: No effects have been observed.
Undesirable effects:
Body as a whole: abdomen enlarged, allergic reaction, asthenia, back pain, chest pain, substernal chest pain, facial edema, peripheral edema, hot flushes, fatigue, fever, flu-like disorder, generalized edema, leg edema, malaise, pain, rigors;
Cardiovascular: flushing, hypertension, tachycardia;
Endocrine: goiter.
Gastrointestinal: bowel irregularity, constipation, aggravated dyspepsia, dysphagia, dysplasia GI, epigastric pain, eructation, esophageal disorder, frequent stools, gastroenteritis, GI hemorrhage, GI symptoms not otherwise specified, hiccup, melena, mouth disorder, pharynx disorder, rectal disorder, serum gastrin increased, tongue disorder, tongue edema, ulcerative stomatitis ,vomiting;
Hearing: earache, tinnitus.
Hematologic: anemia, hypochromic anemia, cervical lymphadenopathy, epistaxis, leukocytosis ,leukopenia and thrombocytopenia.
Hepatic: bilirubinemia, hepatic function abnormal, SGOT increased, SGPT increased;
Metabolic/Nutritional: glycosuria, hyperuricemia, hyponatremia, increased alkaline phosphatase, thirst, vitamin B12 deficiency, weight increase, weight decrease.
Musculoskeletal: arthralgia, arthritis, aggravated, arthropathy, cramps, fibromyalgia syndrome, hernia, polymyalgia rheumatic.
Nervous system /Psychiatric: anorexia, apathy, appetite increased, confusion, depression aggravated, dizziness, hypertonia, nervousness, hypoethesia, impotence, insomnia, migraine, migraine aggravated, paresthesia, sleep disorder, somnolence, tremor, vertigo, visual field defect.
Reproductive: dysmenorrheal, menstrual disorder, vaginitis;
Respiratory: asthma aggravated, coughing, dyspnea, larynx edema, pharyngitis, rhinitis, sinusitis.
Skin and appendages: acne, angioedema, dermatitis, pruritus, pruritus ani, rash, rash erythematous, rash maculopapular, skin inflammation, sweating increased, urticaria.
Special senses: otitis media, parosmia, taste loss, taste perversion.
Urogenital: abnormal urine, albuminuria, cystitis, dysuria, fungal infection, hematuria, micturation frequency, moniliasis, genital moniliasis, polyuria.
Visual: conjunctivitis, vision abnormal.
The following potentially clinically significantly laboratory changes in clinical trials, irrespective of relationship to Nexium were reported in ≤ 1% of patients: increased creatinine, uric acid, total bilirubin, alkaline phophatase, ALT, AST, hemoglobin, white blood cell count, platelets, serum gastrin, potassium, sodium, thyroxine, and thyroid stimulating hormone. Decreases were seen in hemoglobin, white blood cell count, platelets, potassium, sodium, and thyroxine.
Endoscopic findings that were reported as adverse reactions include: duodentitis, esophagitis, esophageal stricture, esophageal ulceration, esophageal varices, gastric ulcer, gastritis, hernia, benign polyps or nodules, Barrett's esophagus and mucosal discoloration.
The incidence of treatment-related adverse reactions during 6 months maintenance treatment was similar to placebo. There were no differences in types of related adverse reactions seen during maintenance treatment up to 12 months compared to short-term treatment.
Two placebo-controlled studies were conducted in 710 patient for treatment of symptomatic gastroesophageal reflux disease. The most common adverse reactions that were reported as possibly or probably related to Nexium were diarrhea (4.3 %), headache (3.8%), abdominal pain (3.8 %).
Combination Treatment with Amoxicillin and Clarithromycin:
In clinical trials using combination therapy with Nexium plus amoxicillin and clarithromycin, no additional adverse reactions specific to these drug combinations were observed. adverse reactions that occurred were limited to those observed were using Nexium, amoxicillin or clarithromycin alone.
The most frequently reported drug-related adverse reactions for patients who received triple therapy for 10 days were diarrhea (9.2 %), taste perversion (6.6%), abdominal pain (3.7%). No treatment-emergent adverse reactions were observed at higher rates with triple therapy than were observed with Nexium alone.
For more information on adverse reactions with amoxicillin or clarithromycin refer to their package inserts, Adverse Reactions section.
In clinical trials using combination therapy with Nexium plus amoxicillin and clarithromycin, no additional increased laboratory abnormalities particular to these drug combinations were observed.
For more information on laboratory changes with amoxicillin or clarithromycin refer to their package inserts, Adverse Reactions section.
Postmarketing Experience:
The following adverse reactions have been identified during post-approval use of Nexium. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a casual relationship to drug exposure.

V.02 33x16.5

إزماتـك كبسولات

إيزوميبرازول ماغنسيوم

إقرأ نشرة معلومات المريض الموجودة بالإزماتك قبل بدء إستخدامه وكل مرة تشتري عبوة جديدة فقد يكون هناك معلومات جديدة. هذه النشرة لا تغني عن التحدث مع طبيبك عن حالتك الصحية وعلاجك.
إن كان لديك أية أسئلة عن إزماتك ،إسأل طبيبك.

ما هو إزماتك ؟

- إزماتك دواء يتم وصفه عن طريق الطبيب أو الصيدلي يدعى مثبط مضخة البروتونات.

إزماتك يستخدم مع الكبار:

- لعلاج أعراض إرتجاع المريء. وإزماتك يوصف أيضا لعلاج تلف في بطانة المريء المرتبط بحامض (التهاب المريء المتآكل) ويساعد على إستمرار الشفاء.
- مرض إرتجاع المريء هو حالة مزمنة (تظل لفترة طويلة) وهى تحدث عندما تعود أحماض المعدة إلى المريء (أنبوبة الغذاء) مسببة الأعراض التالية :
- حرقان في المعدة أو التهاب بالجدار الميطن للمريء . أعراض عامة متضمنة حرقان في المعدة والتي لا تزول، طعم لاذع أو مر بالفم وصعوبة بالبلع .
- لتقليل مخاطر قرح المعدة مع المرضى الذين يستخدمون مضادات الالتهاب غير الاستيرودية.
- لعلاج المرضى ذوى عدوى بالمعدة(هليكوبكتر بيلورى)، مع المضادات الحيوية، أموكسيسيللين،كلاريثروميسين
- للعلاج طويل الأمد لمتلازمة زوليجر إليسون وهى حالة نادرة تنتج المعدة فيها كمية من الأحماض أكثر من الطبيعي.
- للأطفال والمراهقين١ - ١٧ سنة قد يوصف الإيزوميبرازول لفترة قصيرة لعلاج إرتجاع المرئ.

- لا يوصى باستخدام إزماتك للأطفال أقل من سنة.

من الذين يجب ألا يتناولوا إزماتك ؟

لا تتناول إزماتك إذا كنت :

- لديك حساسية من أي من مكونات الإزماتك. أنظر نهاية النشرة لمعرفة مكونات الإزماتك كاملة.
- لديك حساسية لأي دواء آخر مثبط لمضخات البروتونات.

ما يجب أن تخبر به الطبيب قبل تناول إزماتك ؟

إخبر طبيبك عن كل حالتك المرضية كاملة متضمنة إذا كنت :

- تعاني من خلل بالكبد.
- حامل أو تعتقدى أنه قد تكونى حامل أو تخططى لحدوث حمل.
- ترضعين أو تخططى أن ترضعى تحدثى مع طبيبك عن أفضل طريقة لإرضاع طفلك إذا كنت تتناولين الإزماتك.

اخبر طبيبك عن كل الأدوية التي تتناولها سواء كانت موصوفة من طبيب أو غير موصوفة، فيتامينات وأدوية عشبية. إزماتك قد يؤثر على عمل الأدوية الأخرى وقد تؤثر أدوية أخرى على عمل الإزماتك

وأخبر طبيبك خاصة إذا كنت تتناول أي من الآتي :

- وارفارين.
- كيتوكونازول.
- فيريكونازول.
- أتازانافير .
- نيلفينافير .
- ساكينافير.
- المستحضرات التى تحتوى على حديد.
- ديجوكسين.
- سيلستازول : حيث يحتاج إلى تخفيض جرعة السيلستازول من ١٠٠مجم إلى ٥٠ مجم مرتين في اليوم لأنه يؤثر على أيض المستحضر.

كيفية تناول الإزماتك:

- تناول الإزماتك كما وصفه لك الطبيب تماما
- لا تعدل أو توقف جرعة الإزماتك بدون أن تخبر طبيبك
- تناول إزماتك قبل الأكل بساعة
- ابتلع الكبسول كاملا لا بمضغ ولا يكسر
- إذا كان لديك صعوبة فى بلع الكبسول يمكن فتح الكبسول وتفريغ الكريات في نصف كوب ماء غير فوار، ويجب عدم استخدام اي سوائل أخري لانها قد تذيب الكسوة المعوية. قلب الكريات في الماء وأشرب السائل مع الكريات فورا أو خلال ٣٠ دقيقة. اشطف الكوب المستخدم بنصف كوب ماء واشربه. يجب عدم مضغ أو كسر الكريات.
- إذا نسيت جرعة الإزماتك تناولها فور أن تذكرتها. إذا تذكرتها في موعد الجرعة التالية لا تتناول الجرعة المنسية وتناول الجرعة التالية في موعدها ولا تتناول جرعة مضاعفة عوضا عن المنسية.
- إذا تناولت جرعة كبيرة جدا من الإزماتك أخبر طبيبك فورا.
- أنظر في " تعليمات المريض عن كيفية الإستخدام " في نهاية النشرة عن كيفية إستخدام إزماتك كبسولات عن طريق الفم.

ما هي الأعراض الجانبية المحتملة للإزماتك ؟

الأعراض الجانبية الشائعة للإزوميبرازول قد تتضمن :

- صداع.
- إسهال.
- دوخة.
- غازات.
- ألم بالبطن.
- إمساك.
- جفاف بالفم.
- دوار.
- كسور بالعظم.

أخبر طبيبك في حالة ظهور أي عرض يضايقك أو لا يزول هذه ليست كل الأعراض الجانبية للإزماتك تحدث مع طبيبك أو الصيدلي إذا كانت لديك أية استفسارات عن الأعراض الجانبية.

نصيحة عامة:

قد يتم وصف بعض الأدوية لأغراض غير المنصوص بها في نشرة تعليمات المريض. لا تستخدم إزماتك في حالة غير التي تم وصفها لها. لا تعطى إزماتك إلى آخرين ، حتى ولو كانوا يعانوا من نفس الأعراض التي كنت تعانى منها . قد يضرهم ذلك.

- نشرة تعليمات المريض تحتوى على ملخص لأهم المعلومات عن الإزماتك لمزيد من المعلومات اسأل طبيبك . تستطيع سؤال طبيبك أو الصيدلي عن أي معلومات قد تم كتابتها في الجزء المخصص لمتخصصى الرعاية الصحية.

تحذيرات:

- تناول مثبط لمضخات البروتونات قد يسبب إنخفاض مستويات الماغنيسيوم في الدم (نقص ماغنيسيوم الدم) إذا تم تناولها لفترات طويلة (في معظم الحالات ، أكثر من سنة واحدة)، مكملات الماغنيسيوم وحدها لن تحسن إنخفاض مستويات الماغنيسيوم في الدم وكان يجب إيقاف مثبط لمضخات البروتونات.
- إنخفاض مستويات الماغنيسيوم في الدم يؤدي إلي أثار جانبية خطيرة وتشمل تشنج بالعضلات، عدم انتظام ضربات القلب، تشنجات ؛ ومع ذلك لا تحدث هذه الأعراض دائما مع المرضى.علاج نقص الماغنيسيوم بالدم يحتاج عموما تناول مكملات الماغنيسيوم. علاج المرضي الذين يتناولون مثبط لمضخات البروتونات ويعانوا من نقص الماغنيسيوم بالدم يحتاج الي إيقاف مثبط لمضخات البروتونات.
- كسر العظام.

"نشرت العديد من الدراسات الرصدية تشير إلى أن مثبطات مضخة البروتون قد يرتبط مع زيادة خطر هشاشة العظام ذات الصلة لكسور العظام. وتزيد الخطورة في المرضى الذين يتلقوا جرعة عالية، كما هو محدد جرعات يومية متعددة ، لفترات طويلة (سنة أو أكثر). ينبغي على المرضى إستخدام أقل جرعة وأقصر مدة للعلاج بمثبط لمضخات البروتونات. عند علاج المرضى المعرضين لخطر هشاشة العظام ذات الصلة بالكسور يجب إتباع الإرشادات العلاجية الثابتة ".

ما هي مكونات إزماتك ؟

- المواد الفعالة :

كل كبسولة تحتوى على إيزوميبرازول ماغنسيوم ترايهيدرات مكافئ إيزوميبرازول ٤٠ مجم أو ٢٠ مجم .

- المواد الغير فعالة:

مانيتول، ساكروز، كاربونات الكالسيوم، كروسبوفيدون، صوديوم لوريل سالفات، كروسكارميلوز صوديوم، هيبروميلوز، بوفيدون ك ٣٠، بروبايلين جلايكول، هيبروميلوز، فيثالات، ستيئيل كحول، تيرساتين.

العبوة :

إزماتك ٢٠ : علبة كارتون تحتوى على ١ شريط به ٧ كبسولات والنشرة الداخلية.
إزماتك ٤٠ : علبة كارتون تحتوى على ١أو ٢ شريط به ٧ كبسولات والنشرة الداخلية.

كيفية تخزين إزماتك ؟

- يحفظ في درجة حرارة لا تتعدى ٣٠ درجة مئوية.
- يحفظ إزماتك وباقى الأدوية بعيداً عن متناول الأطفال.

إنتاج:

المجموعة المصرية للصناعات الدوائية

EGPI

These reports are listed below by body system:

Blood and Lymphatic: agranulocytosis, pancytopenia.
Eye: blurred vision.
Gastrointestinal: pancreatitis, stomatitis.
Hepatobiliary: hepatic failure, hepatitis with or without jaundice.
Immune system: anaphylactic reaction /stock.
Infections and infestations: GI candidiasis.
Musculoskeletal and Connective Tissue: muscular weakness, myalgia, bone fracture.
Nervous system: hepatic encephalopathy, taste disturbance.
Psychiatric: aggression, agitation, depression, hallucination.
Renal and Urinary: interstitial nephritis.
Reproductive system and Breast: gynecomastia.
Respiratory, Thoracic and Mediastinal: bronchospasm.
Skin and Subcutaneous Tissue: alopecia, erythema multiforme, hyperhidrosis, photosensitivity, Stevens-Johnson syndrome, toxic epidermal necrolysis (some fatal).

Overdose: There is very limited experience to date with deliberate overdose. The symptoms described in connection with 280 mg were gastrointestinal symptoms and weakness. Single dose of 80 mg esomeprazole were uneventful. No specific antidote is known. Esomeprazole is extensively plasma protein bound and therefore not readily dialyzable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilized.

Pharmacodynamic properties:

Pharmacotherapeutic group: proton pump inhibitor.

Esomeprazole is S-isomer of omeprazole and reduces gastric acid section through a specific targeted mechanism of action. It is a specific inhibitor of acid pump in the parietal cell. Both R- and S- isomer of omeprazole have similar pharmacodynamic activity.

Site and mechanism of action:

Esomeprazole is a weak base and is concentrated and converted to the active form of highly acidic environment of the secretory canaliculi of the parietal cell, where it inhibits the enzyme H+ K+ ATPase –the acid pump and inhibits both basal and stimulated acid secretion.

Effect on gastric acid secretion:

After oral dosing of esomeprazole 20 mg and 40 mg the onset of effect occurs within one hour. After repeated administration of 20 mg esomeprazole once daily for five days, mean peak acid output after pentagastrin stimulation is decreased 90 % when measured 6 -7 hours after dosing on day five. After five days of oral dosing with 20 mg and 40 mg of esomeprazole, intragastric PH above 4 was maintained for a mean time of 13 hours and 17 hours. Respectively over 24 hours in symptomatic GERD patients. The proportion of patients maintaining an intragastric PH above 4 for at least 8,12 and 16 hours respectively were for esomeprazole 20 mg 76%, 54% and 24% corresponding proportions for esomeprazole 40 mg were 97%, 92% and 56%.Using AUC as surrogate parameter for plasma concentration, a relationship between inhibition of acid secretion and exposure has been shown.

Therapeutic effects of acid inhibition:

Healing of reflux esophagitis with esomeprazole 40 mg occurs in approximately 78 % of patients after four weeks and 93% after eight weeks.One week treatment with esomeprazole 20 mg b.i.d. and appropriate antibiotics, results in successful eradication of Helicobacter pylori in approximately 90 % of patients. After eradication treatment for one week there is no need for subsequent monotherapy with antisecretory drugs for effective ulcer healing and symptom resolution in uncomplicated duodenal ulcers.

Other effects related in acid inhibition :

During treatment with antisecretory drugs serum gastrin increases in response to the decreased acid secretion. An increased number of ECL cells possibly related to the increased serum gastrin levels, have been observed in some patients during long term treatment with esomeprazole.

During long-term treatment with antisecretory drugs serum gastric glandular cysts have been reported to occur at a somewhat increased frequently. These changes are physiological consequence of pronounced inhibition of acid secretion, are benign and appear to reversible.

In two studies with ranitidine as an active comparator, Esomeprazole showed better effect in healing of gastric ulcers in patients use NSAIDs, including COX-2 selective NSAIDs.

In two studies with placebo as comparator, Esomeprazole showed better effect in the prevention of gastric and duodenal ulcers in patients using NSAIDs (aged › 60 and /or with previous ulcer), including COX-2 selective NSAIDs.

Pharmacokinetic Properties; *Absorption and distribution:* Esomeprazole is acid labile and administrated orally as enteric-coated granules. In vivo conversion to R- isomer is negligible. Absorption of esomeprazole is rapid, with peak plasma levels occurring approximately 1- 2 hours after dose. The absolute bioavailability is 64 % after a single dose of 40 mg and increases to 89 % after repeated once-daily administration .For 20 mg Esomeprazole the corresponding values are 50 % and 68 % respectively. The apparent volume of distribution at steady state of healthy subject is approximately 0.22 L/kg body weight.

Esomeprazole is 97% plasma protein bound.

Food intake both delays and decreases the absorption of esomeprazole although this has no significant influence on the effect of esomeprazole on intragastric acidity.

Metabolism and Excretion:

Esomeprazole is completely metabolized by cytochrome P450 system (CYP)

The major part of the metabolism of esomeprazole is dependent on polymorphic CYP2C19, responsible for the formation of the hydroxy - and desmethyl metabolites of esomeprazole.

The remaining part is dependent on another specific isoform, CYP3A4 responsible for the formation of esomeprazole sulphone, the main metabolite in plasma.

The parameters below reflect mainly pharmacokinetics in individuals with a functional CYP2C19 enzyme, extensive metabolisers.

Total plasma clearance is about 17L/h after a single dose and about 9 L/h after repeated administration. The plasma elimination half-life is about 1.3 hours after repeated once –daily dosing. The pharmacokinetics of esomeprazole has been studied in doses up to 40 mg b.i.d. The area under the plasma concentration-time curve increases with repeated administration of esomeprazole. This increase is dose-dependent and results in a more than dose proportional increase In AUC after repeated administration. This time-and dose-dependency is due to a decrease of first pass metabolism and systemic clearance probably caused by an inhibition of the CYP2C19 enzyme by esomeprazole and/or its sulphone metabolite. Esomeprazole is completely eliminated from plasma between doses with no tendency accumulation during once-daily administration.

The major metabolites of esomeprazole have no effect on gastric acid secretion.

Almost 80 % of an oral dose of esomeprazole is excreted as metabolites in the urine, the remainder in the feces, less than 1 % of the parent drug is found in urine.

Special patient populations: Approximately 2.9±1.5%of population lack of a functional CYP2C19 enzyme and are called poor metabolisers. In these individuals the metabolism of esomeprazole is probably mainly caused by CYP3A4. After repeated once daily administration of 40 mg esomeprazole, the main area under the plasma concentration-time curve was approximately 100 % higher in poor metabolisers than in subjects having a functional CYP2C19 enzyme (extensive metabolisers).

Main peak plasma concentrations were increased by 60%.

The metabolism of esomeprazole is not significantly changes in elderly subjects (71 – 80 years of age).

Following 40 mg of esomeprazole the mean area under the plasma concentration-time curve is approximately 30 % higher in females than in males. No gender difference is seen after repeated once-daily administration.

These finding have no implications for the posology of esomeprazole.

Impaired organ function: The metabolisim of esomeprazole in patients with mild to moderate liver dysfunction may be impaired. The metabolic rate is decreased in patients with severe liver dysfunction resulting a doubling of the area under the plasma concentration-time curve of esomeprazole;Therefore, a maximum of 20 mg should not be exceeded in patients with severe dysfunction. Esomeprazole or its major metabolites do not show any tendency to accumulate with once-daily dosing.

No studies have been performed in patients with decreased renal function. Since the kidney is responsible for the excretion of metabolites of esomeprazole but not for the elimination of the parent compound, the metabolism of esomeprazole is not expected to be changed in patients with impaired renal function .

Pediatrics: Adolescents 12 – 18 years, Following the repeated dose administration of 20 mg and 40 mg esomeprazole, the total exposure (AUC) and the time to reach maximum plasma drug concentration (tmax) in 12 – 18 years old was similar to that in adults for both esomeprazole doses.

Composition:

Each capsules contains:

Active Ingredients:

- Esomeprazole magnesium trihydrate 22.2 mg (equivalent to esomeprazole 20 mg)
- Esomeprazole magnesium trihydrate 44.4 mg (equivalent to esomeprazole 40 mg)

Inactive ingredients: Mannitol, sucrose, calcium carbonate, crospovidone, sodium lauryl sulphate, croscarmellose sodium, hypromellose, povidone k30, propylene glycol, hypromellose, phthalate, cetyl alcohol, triacetin.

Storage: Storage temperature not exceeding 30˚C.

Pack size:

Esmatac 20 :Carton Box Contain one (AL/PVC) strip each of 7 capsules with inner leaflet.
Esmatac 40 :Carton Box Contain one or two (AL/PVC) strip each of 7 capsules with inner leaflet .

Manufactured by:
Egyptian Group for Pharmaceutical Industries.

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