

A. INGREDIENT NAME:

TINIDAZOLE:

B. Chemical Name:

1-(2-ethylsulphonylethyl)-2-methyl-5-nitroimidazole

C. Common Name:

Fasigin

D. Chemical grade or description of the strength, quality, and purity of the ingredient:

Assay: 99.36% dry basis

E. Information about how the ingredient is supplied:

An almost white or pale yellow, crystalline powder, odorless.

F. Information about recognition of the substance in foreign pharmacopeias:

British Pharmacopeia 1993

G. Bibliography of available safety and efficacy data including peer reviewed medical literature:

Ripa, T. The plasma half-life was about 13 hours. *Chemotherapy, Basle*, 1977; 14: 1084.

Jokipii, A. M. M Concentrations in the CSF. *J antimicrob. Chemother.*, 1977; 3: 239.

Sawyer, P. R. A review of tinidazole in the treatment of trichomoniasis, amoebiasis, and giardiasis. *Drugs*, 1976; 11: 423.

Wüst, J. Figures achieved with metronidazole and ornidazole. *Antimicrob, Ag Chemother.* 1977; 11: 631.

1998-3454B1-02-42-BDL2-a

Wise, R. The median minimum inhibitory concentration of tinidazole against *Bacteroides*. *Chemotherapy, Basle*, 1977; 23: 19.

Klastersky, J. The activities of clindamycin, tinidazole, an doxycycline in vitro. *Antimicrob. Ag. Chemother.*, 1977; 12: 563.

Bakshi, J. S. Amoebiasis. *Drugs*, 1978; 15(Suppl): 1, 33.

Apte, V. V. and Packard, R. S. Excellent response was achieved in patients with trichomonal vaginitis. *Drugs*, 1978; 15(Suppl 1): 43.

Welch, J. S. A single dose of tinidazole was as effective as the longer regimen. *Med J Aust.*, 1978; 1: 469.

Levi, G. C. A cure-rate in patients with giardiasis treated with tinidazole. *Am J trop Med Hyg.* 1977; 26: 564.

Anjaneyulu, R. Trichomoniasis. *J int. med Res.*, 1977; 5: 438.

H. Information about dosage forms used:

Capsules

I. Information about strength:

150mg twice a day

J. Information about route of administration:

Orally

K. Stability data:

Manufacture Date: June 1997

Expiration Date: June 2002

Store in a well-closed container, protected from light.

L. Formulations:

M. Miscellaneous Information:

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No.	Records	Request
1	730	tinidazole
2	3139102	PY >= "1990"
3	197	#1 and (PY >= "1990")
4	6511984	LA = "ENGLISH"
5	164	#3 and (LA = "ENGLISH")
6	5831327	TG = "HUMAN"
7	129	#5 and (TG = "HUMAN")

Record 1 of 129 - MEDLINE EXPRESS (R) 1/98-6/98

TI: Helicobacter pylori, efficacy of the new triple therapy in six and twelve-day schedules.
 AU: Perez-Mota-A; Alberdi-JM; Pita-L; Galan-JL; Garcia-Benito-MD; Crespo-L; Blanco-MA; Guemes-C; Villalgorido-C; Carnicero-JA; Beckford-C; Perez-Munoz-C; Fernandez-Velazquez-J; Casanova-A

SO: Rev-Esp-Enferm-Dig. 1997 Dec; 89(12): 879-84

ISSN: 1130-0108

LA: ENGLISH; SPANISH

AB: OBJECTIVE: Assessment of four eradicating patterns of 6 and 12 days duration with new triple therapies adapted to our environment. PATIENTS: After an endoscopic diagnosis of Duodenal or Gastric Ulcer, and the confirmation of the presence of Helicobacter pylori using a rapid urease test in antral biopsies, 274 patients were treated with one of four eradicating therapies, verifying its efficacy with the C-13 urea breath test, at least one month after the end of the treatment and 10 days after withdrawal of proton pump inhibitors. RESULTS: Maximum eradicating efficacy was achieved with Omeprazole (20 mg/12 hours), Clarithromycin (500 mg/12 hours) and Amoxicillin (1 g/12 hours), given for 12 days (96.6%), and Omeprazole (20 mg/12 hours), Tinidazole (500 mg/12 hours) and Clarithromycin (500 mg/12 hours), also given for 12 days (95.2%). The same drugs and doses, when given during six days, achieved percentages of 78.3% and 82.2% respectively. Results with Tinidazole suggest lack of resistance to this drug in the Community of Madrid.

AN: 98155479

Record 2 of 129 - MEDLINE EXPRESS (R) 1/98-6/98

TI: A four-day low dose triple therapy regimen for the treatment of Helicobacter pylori infection.

AU: Trevisani-L; Sartori-S; Caselli-M; Ruina-M; Verdianelli-G; Abbasciano-V

SO: Am-J-Gastroenterol. 1998 Mar; 93(3): 390-3

ISSN: 0002-9270

LA: ENGLISH

AB: OBJECTIVE: The current guidelines recommend 1-wk triple therapy regimens for eradicating H. pylori infection. Until now, shorter regimens have scarcely been investigated. Azithromycin is a new generation macrolide antibiotic with unusual and favorable pharmacokinetics, and seems to be a very promising agent for innovative anti-H. pylori regimens. We assessed the efficacy and tolerability of a new 4-day low dose triple therapy in comparison with a well established 1-wk triple therapy in the treatment of Helicobacter pylori infection. METHODS: One hundred-sixty consecutive patients with biopsy-proven H. pylori infection were randomized to receive lansoprazole 30 mg b.i.d. on days 1-4, azithromycin 500 mg u.i.d. on days 2-4, and tinidazole 2000 mg u.i.d. on day 3 (LAT group), or 7 days of triple therapy of omeprazole 20 mg u.i.d., clarithromycin 250 mg b.i.d., and tinidazole 500 mg b.i.d. (OCT group). Patients with gastric or duodenal active ulcer received proton pump inhibitors for an additional 4 wk. H. pylori eradication was defined as negative of both rapid urease test and histology on biopsies taken from the gastric body and antrum at least 1 month after the end of treatment. RESULTS: Seven patients in the LAT group and four in the OCT group were lost to follow-up. No significant difference in either efficacy or tolerability was observed between the two regimens. Active ulcers healed in 97.8% of cases with LAT and in 100% of cases with OCT. The eradication rate was 80.8% in the LAT group and 85.5% in the OCT group, considering the per-protocol results, and 73.3% and 81.2%, respectively, considering the intention-to-treat results. Side effects occurred in one LAT patient and in two OCT patients; they were mild and did not interfere with compliance. CONCLUSION: The new proposed ultrashort triple therapy, including lansoprazole, low dose azithromycin for 3 days, and a single dose of tinidazole, appears to be a very effective anti-H. pylori regimen, a simpler, cheaper, well-tolerated, and equally effective alternative to 1-wk triple therapy.

AN: 98176823

Record 3 of 129 - MEDLINE EXPRESS (R) 1/98-6/98

TI: Managing vaginal trichomoniasis resistant to high-dose metronidazole therapy.

AU: Lewis-DA; Habgood-L; White-R; Barker-KF; Murphy-SM

SO: Int-J-STD-AIDS. 1997 Dec; 8(12): 780-4

ISSN: 0956-4624

LA: ENGLISH

AN: 98094043

Record 4 of 129 - MEDLINE EXPRESS (R) 1/98-6/98

TI: Therapy of H. pylori infection.

LA: ENGLISH
AB: BACKGROUND: Triple therapy involving a proton pump inhibitor and two antibiotics has been suggested as an effective treatment for Helicobacter pylori infection. The impact of imidazole resistance on the efficacy of such regimens is largely unknown. METHODS: One hundred patients with culture proven H. pylori infection were treated with omeprazole 40 mg b.d., amoxicillin 1000 mg b.d., and tinidazole 500 mg b.d. for one week. Pre-treatment imidazole susceptibility was measured by disk diffusion. Resistance was confirmed by E-test. Eradication was assessed by endoscopy 6-8 weeks after the end of treatment. In cases of doubt a 13C-urea breath test was performed. Side-effects were scored using a semiquantitative scale. RESULTS: H. pylori was eradicated in 95% of the patients with an imidazole-susceptible strain and in 69% of the patients with a resistant strain (P < 0.005). Significant side-effects were seen in 12%. CONCLUSION: This proton pump inhibitor triple therapy is a simple, reasonably effective regimen with few significant side-effects. The efficacy is dependent on the susceptibility of the infecting H. pylori strain.
AN: 97292227

Record 15 of 129 - MEDLINE EXPRESS (R) 1997

TI: Eradication of Helicobacter pylori: an objective assessment of current therapies.

AU: Penston-JG; McColl-KE

SO: Br-J-Clin-Pharmacol. 1997 Mar; 43(3): 223-43

ISSN: 0306-5251

LA: ENGLISH

AB: The purpose of the present review was to determine objectively the optimal treatment for the eradication of H. pylori amongst the currently used regimens. A comprehensive literature search provided a data-base relating to the following treatments: dual therapy with an anti-secretory drug plus either amoxicillin or clarithromycin; standard triple therapy, with or without additional anti-secretory drugs; proton pump inhibitor triple therapy; and H2-receptor antagonist triple therapy. Emphasis was placed on intention-to-treat analyses of eradication rates using all of the available evidence. The criteria used to select the optimal treatment were efficacy (eradication rates), frequency of side-effects, simplicity of the regimen (number of tablets per day and duration of treatment) and cost. The analysis showed that proton pump inhibitor triple therapy (that is, a proton pump inhibitor plus any two of amoxicillin, clarithromycin or a nitroimidazole) was the preferred treatment for the eradication of H. pylori. In particular, the 1-week, low-dose regimen with omeprazole plus clarithromycin plus tinidazole produced the highest eradication rates (> 90%) with the lowest frequency of side-effects and at only modest cost.

AN: 97243736

Record 16 of 129 - MEDLINE EXPRESS (R) 1997

TI: Patient factors that predict failure of omeprazole, clarithromycin, and tinidazole to eradicate Helicobacter pylori.

AU: Moayyedi-P; Chalmers-DM; Axon-AT

SO: J-Gastroenterol. 1997 Feb; 32(1): 24-7

ISSN: 0944-1174

LA: ENGLISH

AB: Omeprazole (20 mg od/b.d.), clarithromycin (250 mg b.d.) and tinidazole (500 mg b.d. for 7 days) [OCT] is an effective regimen against Helicobacter pylori. However, treatment fails in 5%-10% of patients and the reasons for this are not clear. We investigated patient factors that independently predicted failure of this regimen. H. pylori-positive patients were prescribed OCT and the success of treatment was evaluated by the 13C-urea breath test at least 4 weeks after completion of therapy. Patients were prospectively interviewed on past medical history of peptic ulcer and H2-receptor antagonist (H2RA) pre-treatment, smoking history, and alcohol intake. Data were also collected on age, gender, and endoscopic diagnosis to determine factors predicting failure of OCT. H. pylori eradication was achieved in 238 of 273 patients [87%-95% confidence intervals (CI), 83%-91%]. Age, alcohol intake, past medical history of peptic ulcer and peptic ulcer at endoscopy were not independently associated with treatment failure. H. pylori eradication with OCT was less successful in women (P = 0.02), in patients who had received H2RA pre-treatment (P = 0.02), and in smokers (P = 0.02) when evaluated by multiple logistic regression. These findings indicate that OCT is less effective in smokers and in patients who receive H2RA pre-treatment suggesting that these agents should be avoided, if possible, before the patient commences therapy. H. pylori eradication was less successful in women; this result needs further evaluation.

AN: 97211293

Record 17 of 129 - MEDLINE EXPRESS (R) 1997

TI: Urticaria during triple therapy for Helicobacter pylori infection: clinical implications.

AU: Delpre-G; Livni-E; Niv-Y

SO: Dig-Dis-Sci. 1997 Apr; 42(4): 728-30

ISSN: 0163-2116

LA: ENGLISH

AN: 97270557

Record 18 of 129 - MEDLINE EXPRESS (R) 1997

TI: Short-term low-dose triple therapy with azithromycin, metronidazole and lansoprazole appears highly effective for the eradication of Helicobacter pylori.

AU: Caselli-M; Trevisani-L; Tursi-A; Sartori-S; Ruina-M; Luzzi-I; Gaudenzi-P; Alvisi-V; Gasbarrini-G

SO: Eur-J-Gastroenterol-Hepatol. 1997 Jan; 9(1): 45-8

ISSN: 0954-691X

LA: ENGLISH

AB: BACKGROUND: Although the OCN (omeprazole, clarithromycin and nitroimidazoles) short-term low-dose regimens are regarded as 'the standard' in the treatment of *Helicobacter pylori* infection, azithromycin is a new-generation, acid-stable macrolide which may prove particularly useful for a new short-term low-dose triple therapy regimen. OBJECTIVE: To further improve OCN eradication treatments by reducing both the number of pills and the total cost. METHODS: A new short-term low-dose triple therapy (LAM) using lansoprazole 30 mg once a day for 1 week, azithromycin 500 mg once a day for 3 days, and metronidazole 250 mg twice a day for the same 3 days, was administered to 60 patients presenting with *H. pylori*-positive gastritis with or without peptic ulcer, and compared with the classic 'Bazzoli regimen' (OCT: omeprazole, clarithromycin, tinidazole) in 60 matched patients. *H. pylori* infection before and after therapy was evaluated by a rapid urease test, conventional histology and toluidine-stained semi-thin sections. Three biopsies from the corpus and three from the antrum were taken during endoscopic examination before and 7-8 weeks after discontinuation of the treatment. Patient compliance, drug tolerance and drug costs were also taken into consideration. RESULTS: *H. pylori* infection was eradicated 7-8 weeks after treatment in 56 of the 60 patients in the LAM group (93.3%), and in 52 of the 57 patients in the OCT group who completed the treatment (91.2%), with no statistical difference. When gastric or duodenal ulceration was present, ulcer healing was observed in all cases. CONCLUSION: The new proposed short-term low-dose triple therapy (LAM) appears to be as effective as the OCT for the eradication of *H. pylori* infection. The new treatment, however, seems to have advantages in terms of drug tolerance, patient compliance and therapy cost.

AN: 97183938

Record 19 of 129 - MEDLINE EXPRESS (R) 1997

TI: A systematic review on the treatment of giardiasis.

AU: Zaat-JO; Mank-TG; Assendelft-WJ

SO: Trop-Med-Int-Health. 1997 Jan; 2(1): 63-82

ISSN: 1360-2276

LA: ENGLISH

AB: To assess the efficacy of treatment of parasitological excretion of cysts and trophozoites and symptoms of patients with giardiasis, a systematic review of published randomized clinical trials was conducted through extensive searches in Medline, Embase and Current Contents from 1966 till 1996 as well as manual reviews of 28 journals. The methodological quality of all trials was assessed by guidelines of the Cochrane Collaboration. Thirty-one trials were included, only one of which had no serious methodological flaws. The mean score of parasitological examination was 4.8 out of a possible 15. There was a considerable effect in cure rate of treatment versus placebo (odds 9.3, 95% CI 4.69-18.4), but all 3 trials in this comparison had serious flaws. Metronidazole treatment over more than 3 days seems to achieve a better parasitological cure rate than other long treatment courses (pooled odds 2.6, 95% 1.7-3.8), but trials are clinically and statistically heterogeneous. Single-dose therapy is as effective as longer treatment courses (pooled odds 0.67, 95% 0.31-1.44). Within the single-dose regimens tinidazole (2 g) reaches a higher parasitological cure rate than other short therapies (pooled odds 55, 95% CI 3.7-8.3) with relatively few side-effects. Placebo-controlled trials with parasitological and clinical outcomes are needed.

AN: 97171031

Record 20 of 129 - MEDLINE EXPRESS (R) 1996

TI: *Helicobacter pylori* gastritis and non-ulcer dyspepsia in childhood. Efficacy of one-week triple antimicrobial therapy in eradicating the organism.

AU: Cucchiara-S; Salvia-G; Az-Zeqeh-N; D'Armiento-FD; De-Petra-MR; Rapagiolo-S; Campanozzi-A; Emiliano-M

SO: Ital-J-Gastroenterol. 1996 Oct-Nov; 28(8): 430-5

ISSN: 0392-0623

LA: ENGLISH

AB: Efficacy of one-week triple antimicrobial therapy (bismuth, tinidazole, amoxicillin) as compared to the same drug combination given for 4 weeks was assessed in children with *Helicobacter pylori* (*H. pylori*) gastritis and non-ulcer dyspepsia. Twenty-six patients (group A) and 30 (group B) had one-week and four-week schedule, respectively. Eradication (absence of organism at endoscopy at least 1 month after ending treatment) was achieved in 84.6% of group A (22) and 83.3% of group B (25), with marked reduction of histological gastritis score in both groups. Among patients with eradicated *H. pylori*, symptoms improved significantly in 14 and 16 patients of group A and B, respectively, but were still present in 17 (8 group A, 9 group B). The latter showed gastroparesis and abnormal gastro-oesophageal reflux at a subsequent diagnostic work-up and improved with prokinetic therapy. In 3 patients of group A and 3 of group B, symptoms improved despite persistence of bacterium into the stomach. Finally, in 3 cases (1 group A, 2 group B) both symptoms and *H. pylori* infection were unchanged. At 6 month follow-up, symptoms were present in 7 patients (3 group A, 4 group B): 6 of them (3 group A, 3 group B) showed *H. pylori* gastritis at endoscopy. We conclude that in children with dyspepsia and *H. pylori* gastritis one-week triple antimicrobial schedule is effective in eradicating bacterium; however, detection of *H. pylori* gastritis in dyspeptic children does not invariably indicate a pathogenic role of the organism in these patients.

AN: 97184814

Record 21 of 129 - MEDLINE EXPRESS (R) 1996

TI: Effect of lansoprazole in mono-, dual-, or triple therapy on *Helicobacter pylori* eradication.

AU: Kawano-S; Murakami-M; Saita-H; Tsuji-S

SO: J-Gastroenterol. 1996 Nov; 31 Suppl 9: 41-3

TINIDAZOLE

Rodent LD50 is > 2 g/kg.

The drug is a possible mutagen and carcinogen. The drug has produced headache, nausea, urticaria, vertigo, unpleasant taste and sleepiness. It has an effect on seizure thresholds.

In rats, doses of 300 mg/kg produced impaired sexual behavior and embryolethality was seen at 600 mg/kg.

This nitroimidazole is used to treat amoebiasis.

REFERENCES

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