A. INGREDIENT NAME:

DILOXANIDE FUROATE

B. Chemical Name:

Entamide 2-Furoate, Furamide, Furamide (Amebicide), 2-Furancarboxylic Acid, 4-((Dichloroacetyl) Methylamino) Phenyl Ester, 4-(N-Methyl-2,2-Dichloroacetamido)phenyl 2-furoate

C. Common Name:

Dichlofurazol, Diclofurazol, Histomibal, Miforon, Furentomin, Furamide, Furamid, Entamizole

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

Assay 99.96%

E. Information about how the ingredient is supplied:

White Crystalline Powder, Odorless, Tasteless

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

BP 1993

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

Botero, D. Amoebiasis. *Trans. R. Soc. Trop. Med. Hyg.*, 1967;61: 769.

Shapiro, M. M. The recurrence-rate of Giardia intestinalis. *Am. J. trop. Med. Hyg.*, *1967*;16: 704.

Nnochiri, E. *J. trop. Med. Hyg.*, 1967;70:224.

1998-345481-02-22-BDL09

Wolfe, M. S. Patients with non-dysenterica symptomatic intestinal amoebiasis. *J. Am. med. Assoc.*, 1973;224:1601.

Knight, R. The treatment of non-dysenterica intestinal amoebiasis. *Gut*, 1973;14145.

Powell, S. J. Patients treated and was considered to have cured liver abscesses. *Ann. Trop. Med. Parasit.*, 1973;67:367.

Salaki, J. S. The successful treatment of a patient with Entamoeba polecki. *Trop. Dis. Bull.* 1990;77:51.

Bhopale, K. K., Pradhan, K. S., and Masani, K. B. Additive effect of diloxanide furoate and metronidazole (Entamizole) in experimental mouse caecal amoebiasis. *Indian Journal of Experimental Biology.* 1995;33(1):73-74.

Pehrson, P. and Bengtsson, E. Treatment of non-invasive amoebiasis. A comparison between tinidazole alone and in combination with diloxanide furoate. *Transactions of the Royal Society of Tropical Medicine & Hygeine*, 1983; 77(6):845-846.

Salaki, J. S., Shirey, J. L., and Strickland, G. T. Successful treatment of symptomatic Entamoeba polecki infection. *American Journal of Tropical Medicine & Hygeine*, 1979;28(2):190-193.

Wolfe, M. S. Nondysenteric intestinal amebiasis. Treatment with diloxanide furoate. *JAMA*, 1973; 224(13):1601-1604.

Huggins, D. Treatment of amebiasis. *Hospital*, 1965; 67(5):1107-1110.

H. Information about dosage forms used:

Tablet

I. Information about strength:

500mg 3 times daily for 5 days or 20mg/kg/daily divided into 3 daily doses for 10 days.

J. Information about route of administration:

Orally

K. Stability data:

Melting point 114C to 116C
Stable (Hazardous Polymerization will not occur)

L. Formulations:

M. Miscellaneous Information:

Database: Medline <1966 to present>

Set	Search	Results
1	diloxanide furoate.tw.	30
2	stability.tw.	54760
3	1 and 2	0
4	from 1 keep 2,4-5,7,12,15,17,19-21,28	11

<1>
Unique Identifier
97321428
Authors
Qureshi H. Ali A. Baqai R. Ahmed W.
Title
Efficacy of a combined diloxanide furoate-metronidazole preparation in the treatment of amoebiasis and giardiasis.
Source
Journal of International Medical Research. 25(3):167-70, 1997 May-Jun.
Abstract
A combined formulation of diloxanide furoate and metronidazole was used to treat amoebiasis and giardiasis (cysts and vegetative forms) in 54 patients. Of these 34 patients had amoebiasis, 19 had giardiasis and one had mixed infection. Each patient took one tablet (containing 500 mg diloxanide furoate and 400 mg metronidazole), three times daily for 5 days, and the response to therapy was checked by clinical examination and by examination of fresh stools on days 3, 5 and 10. Abdominal pain was completely relieved in 91% and 84% of patients with amoebiasis and giardiasis, respectively, while parasitic clearance was 100% in both groups. Tolerance to the drug was adequate.

<2>
Unique Identifier
97281374
Authors
Bhopale KK. Pradhan KS. Masani KB. Kaul CL.
Title
Additive effect of diloxanide furoate and metronidazole (Entamizole) in experimental mouse caecal amoebiasis.
Source
Indian Journal of Experimental Biology. 33(1):73-4, 1995 Jan.

<3>
Unique Identifier
96319050
Authors
Sengupta M. Sengupta O.
Title
Correlation of biological activity (therapeutic and toxic) with solvochromic properties of metronidazole, emetine hydrochloride and diloxanide furoate.
Source
Indian Journal of Biochemistry & Biophysics. 32(5):302-7, 1995 Oct.
Abstract
Goat blood, when incubated for different periods with diloxanide furoate, metronidazole and emetine hydrochloride, underwent changes in fatty acid constituents and their peroxidation products measured as malonaldehyde. These findings, together with the changes noted in the drug-lipid partition coefficient, are discussed in an attempt to correlate the lipid constitution and biological activity of the drugs.

<4>
Unique Identifier
84122526
Authors
Pehrson P. Bengtsson E.
Title
Treatment of non-invasive amoebiasis. A comparison between tinidazole alone and in combination with diloxanide furoate.
Source
Transactions of the Royal Society of Tropical Medicine & Hygiene. 77(6):845-6, 1983.
Abstract
Tinidazole (40 mg/kg body-weight in one daily dose for five days) and tinidazole (same dose) plus diloxanide furoate (20 mg/kg body-weight divided into three daily doses for 10 days) were compared as treatments for amoebiasis. The parasitic cure rates were 44 and 91% respectively. We cannot, therefore, recommend tinidazole alone in this dosage as a treatment for non-invasive amoebiasis.

<5>
Unique Identifier

than in the non-aspirated group, particularly for patients whose lesion size was more than 6 cm (P less than 0.01). In conclusion, percutaneous needle aspiration is safe, enhances clinical recovery, and accelerates resolution particularly in patients with large abscess cavities.

AN: 91024358

Record 17 of 17 - MEDLINE EXPRESS (R) 1984-1990

TI: Treatment of asymptomatic amebiasis in homosexual men. Clinical trials with metronidazole, tinidazole, and diloxanide furoate.

AU: Thoren-K; Hakansson-C; Bergstrom-T; Johanisson-G; Norkrans-G

SO: Sex-Transm-Dis. 1990 Apr-Jun; 17(2): 72-4

ISSN: 0148-5717

LA: ENGLISH

AB: In a randomized trial, the authors treated 42 asymptomatic homosexual men who had Entamoeba histolytica in fecal specimens with either metronidazole or tinidazole (study 1). They treated both groups initially with 2,000 mg in a single dose, and in case of failure with 2,000 mg daily for 5 days. In cases of repeated failure, the authors prescribed a dosage of 500 mg of diloxanide furoate three times per day (TID) for 10 days. In a subsequent study (study 2) the authors treated 49 asymptomatic homosexual men who had E. histolytica in fecal specimens with 500 mg of diloxanide furoate TID for 10 days. In study 1, the parasitological cure rates (PCR) for metronidazole and tinidazole were 29%-56%. Among the men treated with diloxanide furoate, the PCR was 93%. In study 2 the PCR with diloxanide furoate was 88%, which was significantly better (P less than .05) than metronidazole/tinidazole treatment in study 1. The present studies show that diloxanide furoate is an effective treatment of amebiasis in asymptomatic patients.

AN: 90296217

DILOXANIDE FUROATE

Mouse oral LD50 >710 mg/kg.

Toxicological properties have not been thoroughly investigated. It has produced vomiting, urticaria, pruritis, flatulence and G.I. distress. May have induced eosinophilia in some people.

Has been used with tinidazole as an antiprotozoal combination.

REFERENCES

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2. Bhopale KK, Pradhan KS, Masani KB, et al. Additive effect of diloxanide furoate and metronidazole (Entamizole) in experimental mouse caecal amoebiasis. Indian J Exp Biol 1995; 33(1):73-4.

3. Sengupta M, Sengupta O. Correlation of biological activity (therapeutic and toxic) with solvochromic properties of metronidazole, emetine hydrochloride and diloxanide furoate. Indian J Biochem Biophys 1995; 32(5):302-7.

4. Pehrson P, Bengtsson E. Treatment of non-invasive amoebiasis. A comparison between tinidazole alone and in combination with diloxanide furoate. Trans R Soc Trop Med Hyg 1983; 77(6):845-6.

5. Salaki JS, Shirey JL, Strickland GT. Successful treatment of symptomatic Entamoeba polecki infection. Am J Trop Med Hyg 1979; 28(2):190-3.

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9. Huggins D. [Treatment of amebiasis. (Results obtained with diloxanide furoate)]. [Portuguese] Hospital 1965; 67(5):1107-10.

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13. Bhopale KK, Pradhan KS, Masani KB, et al. A comparative study of experimental caecal amoebiasis and the evaluation of amoebicides. Ann Trop Med Parasitol 1995; 89(3):253-9.

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