

FOLIC ACID

FOLART

5 mg/5 mL SYRUP
2.5 mg/mL DROPS
Anti-Anemic

The FIRST PURE FOLIC ACID SYRUP AND DROPS for the PREVENTION & TREATMENT of Anemias, Malabsorption in Diarrhea and Low Birth Weight

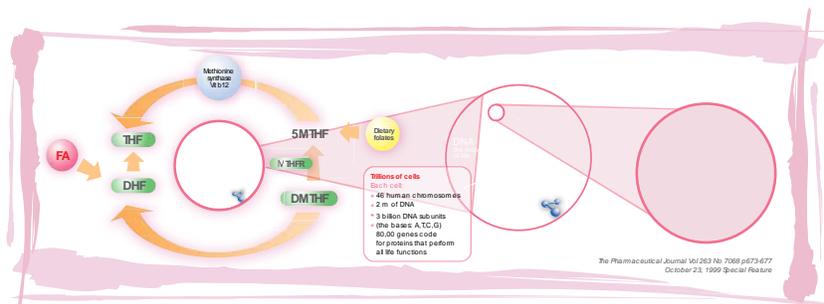
FOLIC ACID IN INFANCY

Diarrhea

-Folic acid was chosen because of its importance in cellular DNA synthesis and may help in the repair of the damaged villous cells of the small bowel. This is how it may help in rotaviral diarrhoea, which damages the villous tips. But there were equally good results in patients with non rotaviral diarrhoea. No infants in the same population had shown any evidence of folate deficiency in an earlier pilot study.

-Haffejee et. al. carried out a controlled clinical study of 76 infants and young children admitted to the hospital with acute diarrhea. Patients receiving an oral dose of 5 mg/8 hrs of folic acid recovered in a significantly shorter time (mean 53hrs) than those not given folic acid (mean of 93hrs). All received ORT and there were no adverse side effects of the folate.

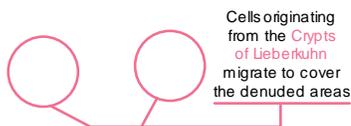
-It appears that this non-allergenic, cheap and readily available therapy could play an important role in shortening the duration of childhood diarrhea and possibly in preventing or modifying persistent diarrhea.



-Haffejee et. al. Department of Pediatrics and Child Health, University of Natal, Congella, South Africa. 1988

During Diarrhea

- especially rotaviral : infantile diarrhea watery
6 to 24 months of age



- Intensive mitosis (cell proliferation)
- Increased demand for DNA
- Increased demand for folate

Folic and Folinic Acid Blood Levels in Infants with Diarrhea,

Malnutrition and Infection.

-Whole blood folic acid levels were found by Izac et. al. to range in normal adults from 50 mcg/ml to 150 mcg/ml with a mean of 89 mcg/ml while infants showed slightly lower levels of 79.2 +/- 39.2 mcg/ml.

-Results of 60 infants with diarrhea were presented. 80% of the infants' folic acid activity were below 40mcg/ml, 50% were below 20 mcg/ml and some showed extremely low folic acid levels of below 10 mcg/ml while infants with malnutrition and recurrent diarrhea had 13.5 mcg/ml.

-The effect of folic acid in the general condition and well being of the patient, as reflected in his mood, appetite and weight gain was dramatic in some cases. Rapidly growing tissues and intensive hematopoiesis call for an increased demand of folic acid. Supplies on the other hand, are limited. The vulnerability of folic acid metabolism in infancy can be understood with the increased demand on the other hand limited supplies. A tendency to low folic acid values in blood, indicating low reserves is found in healthy infants. Any additional strain on these reserves such as infection may produce a frank deficiency state.

-Yehuda Matoth et. al. Sharon Hospital, Research of the Rogoff Medical Research Institute, Bellinson Medical Center, Hebrew University-Hadassah Medical School, Jerusalem, Israel. 1964

Low birth weight

Response of Low Birth Weight infants to treatment with Folic Acid

-A group of 10 infants of low birth weight (1,800 g) were given folic acid. Venous blood levels were collected within 5 days of birth, immediately afterwards the infants received 100 mcg of folic acid by intramuscular injection. The dose was repeated on alternate days for 14 injections. Blood samples were taken on the 17th and 28th day of treatment and also during 3rd, 6th, 9th month of infancy. Results were compared with similar but untreated group of 20 infants. No additional vitamins or supplements were given during treatment.

-The investigation confirmed that a rapid fall of serum folate levels and red cell folate levels occur in low birth weight infants. The study also shows that 1.4 mg of folic acid intramuscularly for 4 months significantly increases serum folate levels and red cell folate levels in low birth weight infants compared to the 20 untreated group.

-The authors suggest that low birth weight infants require prophylactic folate to prevent depletion and subclinical folate deficiency. If stresses such as infection occur in untreated infants, severe deficiency or megaloblastic anemia might occur.

-W.L. Burland et. al. Glaxo Lab, Greenford, Middlesex; St. Barthomew's Hospital, London 1971

Influence of Folic Acid on Low Birth Weight and Growth of Erythroblastotic Infants.

-Seventeen infants with severe (14) or moderately severe (3) erythroblastosis were given daily oral supplements of 2.5 mg or 5 mg folic acid from day 16 to 3 ½ months. Their rate of weight gain, expressed as weight centiles, was followed for 1 year and was compared with that of very similar group of 34 erythroblastotic infants without folic acid supplements. By the end of the 4th month, just after stopping folate intake, the median centiles for weight had risen from the 40th to the 80th centile, while in the untreated control group they rose during this period from the 35th to the 50th centile. During the 2nd half of the year, both group declined in weight centiles, the "treated" group ending up at the 50th centile for weight, while the control group fell to the 25th.

-There was a significant correlation of declining weight centiles with low serum folate levels.

-G.Gandy et. al. Strangeways Research Laboratory, Cambridge Maternity Hospital. 1977

Thalassemia

The effect of Folic Acid Supplementation in Beta Thalassemia Major: A Randomized placebo-controlled Clinical Trial

-51 patients (23 controlled and 28 cases) with b-Thalassemia major undergoing blood transfusions were entered in the study with an age mean of 17 +/- 5 years. Patients were given 1mg folic acid and was asked to return after 4 weeks for blood samples.

-Serum Folate levels of the case group rose from 3.4 +/- 2.5 to 9 +/- 3.6 ng/ml while the control group fell from 4 +/- 4.5 to 3.1 +/- 2.8 ng/ml.

-Encountering Folic acid deficiency with these patients came as a surprise to the authors on their 1st study because their diet were fresh vegetables and usually drink plenty of tea. And even though under transfused, these patients received red cells donated by non folate deficient persons. This shows that patients with thalassemia major needs extra folic acid to fulfill their requirements.

-The authors recommend prophylactic and routine folic acid supplementation for all patients with thalassemia major and intermedia.

-Fereidoon Mojtahedzadeh MD et. al. Bou Ali Sina Hospital, Mazandaran University of Medical Sciences, Sari, Iran. 2005

PRODUCT INFORMATION

FORMULATION:

Drops:

Each mL contains:

Folic Acid.....2.5mg

Syrup:

Each 5 mL contains:

Folic Acid.....5mg

PROPERTIES AND MODE OF ACTION:

Folic acid (pteroylglutamic acid) in its reduced form of tetrahydrofolate serves as an important mediator in many reactions involving one-carbon transfers. Important reaction involves the conversion of homocysteine to methionine and of deoxyuridylate to Aeoxythymidylate, an important step in DNA synthesis. It is also implicated in the conversion of some amino acids, and in the synthesis and utilization of formate. The deficiency of folic acid can lead to megaloblastic anemia, which develops when dietary intake of folic acid is inadequate, such as megaloblastic changes in the bone marrow of several infants with severe diarrhea, malnutrition and other infections; low birth weight and elevated homocysteine level in conditions such as in infants and children with chronic renal failure and heart disease; in reducing the prevalence and severity of neural tube defects in preconception and periconception.

INDICATIONS:

For the prevention and treatment of Vitamin B deficiency, macrocytic anemia, megaloblastic anemia and thalassemia, due to folic acid deficiency. Folic acid supplements may be required in low birth weight infants, infants breast-fed by folic acid-deficient mothers, or those with prolonged diarrhea and infection.

DOSAGE:

Drops:

Infants up to 1 year : 500 mcg/kg daily. Over 1 year (5 mg) as adult dose or as prescribed by a physician.

Syrup:

Over 1 year old: as adult dose or as prescribed by a physician.

CONTRAINDICATIONS:

Megaloblastic anemia secondary to vitamin B12 deficiency. Folic acid administration may produce hematologic remission while neurologic damage progresses. Folic acid should not be given before a diagnosis has been fully established. Large and continuous doses of folic acid may lower the blood concentration of vitamin B12.

PRECAUTIONS:

Caution is advised for patients who may have folate-dependent tumors. Concurrent use with other drugs must be reported to and monitored by a physician and the dose of folic acid adjusted accordingly.

ADVERSE EFFECTS:

Folic acid is generally well tolerated. Rare cases of gastrointestinal disturbances and hypersensitivity reactions have been reported.

INTERACTIONS:

Folic acid metabolism may be affected by anticonvulsants, oral contraceptives, antituberculosis drugs, alcohol, and folic acid antagonists including aminopterin, methotrexate, pyrimethamine, trimethoprim, and sulfonamides which have been said to produce folic acid deficiency states.

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

STORAGE:

Store at temperatures not exceeding 30°C.

AVAILABILITY:

Drops - 30 mL bottle

Syrup - 60 mL bottle

120 mL bottle

Exclusively distributed by:

Folares Pharmaceuticals, Inc.

2F SEDCCO 1 Bldg, Rada St.

Legaspi Village, Makati City

Manufactured by:

Lloyd Laboratories, Inc.

#10 Lloyd Avenue, First Bulacan Industrial City,

City of Malolos, Bulacan

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