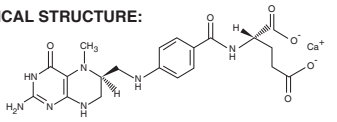
Folat™
(L-Methylfolate)

400 mcg Tablets

DESCRIPTION:
Folat contains folate in the form of L-Methylfolate which is the biologically active folate isomer. L-Methylfolate is the body's preferred form of folate because it is directly usable by the human organism for certain metabolic processes. There are well documented studies which have established folic acid's ineffectiveness regarding inherited disorders of folate transport and metabolism. These disorders limit and impair the capacity to ingest, digest, absorb or metabolize folic acid. Folic acid, the synthetic form of folate, must be metabolized in a four step process by the body to become the biologically active L-Methylfolate.

CHEMICAL STRUCTURE:



QUALITATIVE AND QUANTITATIVE COMPOSITION:
Each film coated tablet contains:
L-Methylfolate MS.....400mcg

INDICATIONS:
Folat tablets are for the specific dietary management of impaired metabolic processes in those women with distinct nutritional requirments for any of the following conditions:
- High risk recurrent pregnancy loss.
- Hyperhomocysteinemia during pregnancy.
- Impaired folic acid absorption and impaired metabolism.
- Breast-feeding.
- Vitamin B12 deficiency.
- To reduce risk of neural tube defects in the developing fetus.
- Anemia during pregnancy

CLINICAL PHARMACOLOGY:
L-Methylfolate or 6(S)-5-methyltetrahydrofolate [6(S)-5-MTHF], is the primary biologically active diastereoisomer of folate and the primary form of folate in circulation. It is also the form which is transported across membranes into peripheral tissues, particularly across the blood brain barrier. In the cell, 6(S)-5-MTHF is used in the methylation of homocysteine to form methionine and tetrahydrofolate (THF). THF is the immediate acceptor of one carbon units for the synthesis of thymidine-DNA, purines (RNA and DNA) and methionine. About 70% of food folate and cellular folate is comprised of 6(S)-5-MTHF. Folic acid, the synthetic form of folate, must undergo enzymatic reduction by methylenetetrahydrofolate reductase (MTHFR) to become biologically active.

PHARMACOKINETICS:
Distribution: L-Methylfolate is naturally stored in most cells and used by the body when needed; therefore, L-Methylfolate may not follow typical drug pharmacokinetic patterns. The volume of distribution and plasma clearance has not been reported.

Absorption & Elimination: L-Methylfolate is a water soluble molecule which is primarily excreted via the kidney. Mean elimination half-life approximately 3 hours for d,l-methylfolate. Peak plasma levels have been reported 1 to 3 hours following administration. The mean values for Cmax and Tmax were 129 ng/ml and 1.3 hr, respectively.The plasma protein binding of L-Methylfolate is 56%.

CONTRAINDICATION:
Folat is contraindicated in patients with known hypersensitivity to any of the components contained in this product.

PRECAUTIONS:
Folic acid, when administered in daily doses above 0.1mg, may obscure the detection of B_{12} deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B_{12} deficiency, including pernicious anemia, while not addressing the neurological manifestations). L-Methylfolate may be less likely than folic acid to mask vitamin B_{12} deficiency.

INTERACTION WITH DRUGS:
L-Methylfolate may reduce plasma levels of certain anticonvulsants, including phenytoin, carbamazepine, Fosphenytoin, Phenobarbital, Primidone, or Valproate L-Methylfolate may reduce plasma levels of Pyrimethamine. Patients taking folate-lowering drugs (e.g., anticonvulsants, Cholestyramine, Colestipol, Cycloserine, Aminopterin, Methotrexate, Sulfasalazine, Pyrimethamine, Triamterene, Trimethoprim, Isotretinoin, Fluoxetine, Nonsteroidal anti-infl ammatory drugs (NSAIDs), Methylprednisolone, Pentamidine) or who smoke or drink heavily may require higher doses of L-Methylfolate

SIDE EFFECTS:
L-Methylfolate is generally well tolerated. However, higher doses may be associated with more side effects, such as:
- Sleeping problems
- Overactivity
- Abdominal (stomach) pain
- Nausea
- Gas

DOSAGE:
The recommended dosage for pregnant women is 800 mcg per day, 2 tablets BID.

STORAGE:
Store below 30°C. Protect from heat, light and moisture.

PRESENTATION:
Folat tablets are available in ALU/PVC Blister pack of 30 tablets.

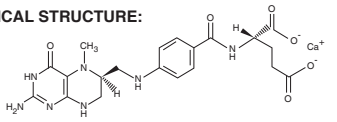
For detailed information please contact:
GENIX
GENIX PHARMA PRIVATE LIMITED
44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.
UAN: +92-21-111-10-10-11, Fax: +92-21-111-10-10-22
E-mail: info@genixpharma.com Web.: www.genixpharma.com

Folat™
(L-Methylfolate)

400 mcg Tablets

DESCRIPTION:
Folat contains folate in the form of L-Methylfolate which is the biologically active folate isomer. L-Methylfolate is the body's preferred form of folate because it is directly usable by the human organism for certain metabolic processes. There are well documented studies which have established folic acid's ineffectiveness regarding inherited disorders of folate transport and metabolism. These disorders limit and impair the capacity to ingest, digest, absorb or metabolize folic acid. Folic acid, the synthetic form of folate, must be metabolized in a four step process by the body to become the biologically active L-Methylfolate.

CHEMICAL STRUCTURE:



QUALITATIVE AND QUANTITATIVE COMPOSITION:
Each film coated tablet contains:
L-Methylfolate MS.....400mcg

INDICATIONS:
Folat tablets are for the specific dietary management of impaired metabolic processes in those women with distinct nutritional requirments for any of the following conditions:
- High risk recurrent pregnancy loss.
- Hyperhomocysteinemia during pregnancy.
- Impaired folic acid absorption and impaired metabolism.
- Breast-feeding.
- Vitamin B12 deficiency.
- To reduce risk of neural tube defects in the developing fetus.
- Anemia during pregnancy

CLINICAL PHARMACOLOGY:
L-Methylfolate or 6(S)-5-methyltetrahydrofolate [6(S)-5-MTHF], is the primary biologically active diastereoisomer of folate and the primary form of folate in circulation. It is also the form which is transported across membranes into peripheral tissues, particularly across the blood brain barrier. In the cell, 6(S)-5-MTHF is used in the methylation of homocysteine to form methionine and tetrahydrofolate (THF). THF is the immediate acceptor of one carbon units for the synthesis of thymidine-DNA, purines (RNA and DNA) and methionine. About 70% of food folate and cellular folate is comprised of 6(S)-5-MTHF. Folic acid, the synthetic form of folate, must undergo enzymatic reduction by methylenetetrahydrofolate reductase (MTHFR) to become biologically active.

PHARMACOKINETICS:
Distribution: L-Methylfolate is naturally stored in most cells and used by the body when needed; therefore, L-Methylfolate may not follow typical drug pharmacokinetic patterns. The volume of distribution and plasma clearance has not been reported.

Absorption & Elimination: L-Methylfolate is a water soluble molecule which is primarily excreted via the kidney. Mean elimination half-life approximately 3 hours for d,l-methylfolate. Peak plasma levels have been reported 1 to 3 hours following administration. The mean values for Cmax and Tmax were 129 ng/ml and 1.3 hr, respectively.The plasma protein binding of L-Methylfolate is 56%.

CONTRAINDICATION:
Folat is contraindicated in patients with known hypersensitivity to any of the components contained in this product.

PRECAUTIONS:
Folic acid, when administered in daily doses above 0.1mg, may obscure the detection of B_{12} deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B_{12} deficiency, including pernicious anemia, while not addressing the neurological manifestations). L-Methylfolate may be less likely than folic acid to mask vitamin B_{12} deficiency.

INTERACTION WITH DRUGS:
L-Methylfolate may reduce plasma levels of certain anticonvulsants, including phenytoin, carbamazepine, Fosphenytoin, Phenobarbital, Primidone, or Valproate L-Methylfolate may reduce plasma levels of Pyrimethamine. Patients taking folate-lowering drugs (e.g., anticonvulsants, Cholestyramine, Colestipol, Cycloserine, Aminopterin, Methotrexate, Sulfasalazine, Pyrimethamine, Triamterene, Trimethoprim, Isotretinoin, Fluoxetine, Nonsteroidal anti-infl ammatory drugs (NSAIDs), Methylprednisolone, Pentamidine) or who smoke or drink heavily may require higher doses of L-Methylfolate

SIDE EFFECTS:
L-Methylfolate is generally well tolerated. However, higher doses may be associated with more side effects, such as:
- Sleeping problems
- Overactivity
- Abdominal (stomach) pain
- Nausea
- Gas

DOSAGE:
The recommended dosage for pregnant women is 800 mcg per day, 2 tablets BID.

STORAGE:
Store below 30°C. Protect from heat, light and moisture.

PRESENTATION:
Folat tablets are available in ALU/PVC Blister pack of 30 tablets.

For detailed information please contact:
GENIX
GENIX PHARMA PRIVATE LIMITED
44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.
UAN: +92-21-111-10-10-11, Fax: +92-21-111-10-10-22
E-mail: info@genixpharma.com Web.: www.genixpharma.com