

# فولی ڈے

# Foliday<sup>TM</sup>

Quatrefolic<sup>®</sup>

## SUPPLEMENT FACTS

### Foliday Tablet:

Each film coated tablet contains:

Folate [Quatrefolic<sup>®</sup> 800mcg as (6S)-5-MTHF, glucosamine salt] (Vegetarian Source).....400mcg

Each film coated tablet contains:

Folate [Quatrefolic<sup>®</sup> 1200mcg as (6S)-5-MTHF, glucosamine salt] (Vegetarian Source).....600mcg

## DESCRIPTION

Foliday tablets contain the glucosamine salt of (6S)-5-methyltetrahydrofolate, which is described as 4th Generation Folate.

### Chronology:

The generations of folate

1st generation folate (food)	2nd generation folate (synthetic folic acid)	3rd generation folate (reduced folate)	4th generation folate (Quatrefolic <sup>®</sup> )
---------------------------------	---	---	--

## PHARMACOLOGICAL PROPERTIES

### Mechanism of action

The mechanism of action of Quatrefolic<sup>®</sup> is related to the action of 5-methyltetrahydrofolate the active part of the proprietary ingredient. 5-methyltetrahydrofolate derives from tetrahydrofolic acid, through a series of metabolic reactions. Tetrahydrofolic acid acts as a coenzyme in several vital metabolic reactions participating in the transfer as acceptors and donors of various one-carbon fragments, involved in the biosynthesis of nucleotides purines and pyrimidines and in the metabolism of several important amino acids. In concern with vitamin B12, folate coenzymes allow the conversion of the amino acid homocysteine to methionine, the lack of this conversion has been associated with various pathologies and diseases. Conversion of tetrahydrofolic acid to 5-methyltetrahydrofolate is mediated by the action of the enzyme methyltetrahydrofolate reductase. Supplementation with 5-methyltetrahydrofolate might be preferable to folic acid, being it is immediately available to react with homocysteine to avoid the possibility of hyperhomocysteinaemia.

## THERAPEUTIC USES

- During pregnancy and lactation
- Pregnant women for prevention of neural tube defect in babies
- As a dietary supplement in adults and older people
- To prevent risk of spontaneous abortions
- In hyperhomocysteinaemia
- Folate deficiency caused by some medicines (e.g. those used to treat epilepsy such as phenytoin, phenobarbital and primidone)
- Folate deficiency caused by long-term red blood cell damage or kidney dialysis
- In Depression, Cognitive impairment, Dementia and Alzheimer's disease

## DOSEAGE AND ADMINISTRATION

The dosage of Foliday tablet will be guided on the basis of the "Recommended Dietary Allowances for Folate in Children and Adults"

AGE (years)	MALES AND FEMALES (mcg/day)	PREGNANCY (mcg/day)	LACTATION (mcg/day)
1-3	150	-	-
4-8	200	-	-
9-13	300	-	-
14-18	400	600	500
19+	400	600	500

## CONTRAINDICATIONS

- Long-term folate therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before long-term folate therapy.
- Folate given to such patients for 3 months or longer has precipitated cobalamin neuropathy. No harm has occurred from short courses of folate.
- Folic acid should never be given alone in the treatment of Addisonian, pernicious anemia and other vitamin B12 deficiency states because it may precipitate the onset of sub-acute combined degeneration of the spinal cord
- Folic acid should not be used in malignant disease unless megaloblastic anemia owing to folate deficiency is an important complication.
- Known hypersensitivity to the active ingredient.

## WARNINGS AND PRECAUTIONS

- Patients with vitamin B12 deficiency should not be treated with folic acid unless administered with adequate amounts of hydroxocobalamin, as it can mask the condition but the sub-acute irreversible damage to the nervous system will continue. The deficiency can be due to undiagnosed megaloblastic anemia including in infancy, pernicious anemia or macrocytic anemia of unknown etiology or other cause of cobalamin deficiency, including lifelong vegetarians.
- Caution should be exercised when administering folic acid to patients who may have folate dependent tumors.
- This product is not intended for healthy pregnant women where lower doses are recommended, but for pregnant women with folic acid deficiency or women at risk for the recurrence of neural tube defects.
- Taking folic acid supplements might make seizures worse in people with seizure disorders, particularly in high doses.

## ADVERSE REACTIONS

### Gastrointestinal disorders

Anorexia, nausea, abdominal distension and flatulence

### Immune system disorders

Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnea, and anaphylactic reactions (including shock)

## DRUG INTERACTIONS

### Fosphenytoin

Folic acid along with fosphenytoin might decrease the effectiveness of fosphenytoin for preventing seizures.

### Methotrexate

Folic acid along with methotrexate might decrease the effectiveness of methotrexate.

### Phenobarbital

Folic acid can decrease the phenobarbital effect for preventing seizures.

### Phenytoin

Folic acid along with phenytoin might decrease the effectiveness of phenytoin and increase the possibility of seizures.

### Primidone

Folic acid along with primidone might decrease how well primidone works for preventing seizures.

### Pyrimethamine

Folic acid might decrease the effectiveness of pyrimethamine for treating parasite infections.

### Sulfasalazine

Sulfasalazine can reduce the absorption of folic acid.

## USE IN SPECIAL POPULATIONS

### Pregnancy

US FDA Pregnancy Category A. Folic acid is likely safe when taken by mouth appropriately during pregnancy. Taking 600 mcg of folic acid daily is commonly used during pregnancy to prevent birth defects and some neural tube defects.

### Nursing mothers

Folic acid is actively excreted into human milk. No adverse effects in nursing infants have been associated with the use of folic acid during lactation.

### Hepatic adjustment

No information available

### Renal adjustment

No information available

## OVERDOSAGE:

Data regarding over dosage reports is lacking. In event of overdose, no special procedures or antidote are likely to be needed.

### Pharmacokinetics

Pharmacokinetic data for the gulosamine salt of (6S)-5-methyltetrahydrofolate is limited. SMTHF glucosamine will readily dissociate to SMTHF and glucosamine in the aqueous environment of the digestive tract.

SMTHF is extensively protein bound. The principal storage site of folate is in the liver; it is also actively concentrated in the CSF. Folate is distributed into breast milk.

The mean plasma half life of folates after SMTHF-glucosamine administration has been found to be 4.5 - 12 hours approximately.

Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine.

## SHELF LIFE

Observe expiry date on the outer pack.

## INSTRUCTIONS

Keep all medicines out of the reach of children.

## SPECIAL PRECAUTIONS FOR STORAGE

Protect from heat, light and moisture.

Do not store above 30°C.

## PRESENTATION

Foliday (Quatrefolic) 400mcg tablets are available in a pack of 30's.

Foliday (Quatrefolic) 600mcg tablets are available in a pack of 30's.

## MANUFACTURED BY:

ASPIN

An OBS Group Company

Aspin Pharma (Pvt.) Ltd.  
Plot No.10 & 25, Sector No. 20,  
Korangi Industrial Area Karachi-74900, Pakistan.

www.aspin.com.pk

## MANUFACTURED BY:

Novamed Healthcare (Pvt.) Ltd.  
28-Km. Ferozepur Road, Lahore - Pakistan

ہدایات:  
بچوں کی پہنچ سے دور رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔

۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں۔

