What is in this leaflet

1. What Folic Acid tablets are and what they are used for

Folic Acid belongs to the vitamin B group. Folic Acid tablets may be used:

to treat:
• folate deficiency anaemia caused by poor diet, poor absorption of food (such as in coeliac disease or a digestive disorder called sprue) or increased use of folate in the body (as in pregnancy)

to prevent:
• 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
• neural tube defects in babies (e.g. spina bifida), where women are at risk of having an affected child.

2. What you need to know before you take Folic Acid tablets

Do not take Folic Acid tablets and tell your doctor if you have:
• an allergy (hypersensitivity) to folic acid or any of the other ingredients in the tablets (see section 6)
• an untreated vitamin B12 deficiency such as in certain anaemias and lifelong vegetarians
• pernicious anaemia (a form of anaemia caused by lack of vitamin B12) or another condition caused by vitamin B12 deficiency
• a malignant (cancerous) disease.

3. Warnings and precautions

Talk to your doctor or pharmacist before taking Folic Acid tablets if you:
• have a folate dependent tumour
• are pregnant
• have any disease that reduces the amount of vitamin B12 in the body.

Other medicines and Folic Acid tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:
• antiepileptics (to treat epilepsy) such as phenytoin, phenobarbital, primidone, sodium valproate and carbamazepine
• antibacterials (to treat infections) such as trimethoprim, chloramphenicol and cotrimoxazole
• sulfasalazine (to treat ulcerative colitis, Crohn's disease or rheumatoid arthritis)
• methotrexate (to treat Crohn's disease, psoriasis or rheumatoid arthritis)
• lithium for mental health problems
• triamterene, a diuretic (or 'water tablet')
• a gas and air mixture to put you to sleep for an operation or to relieve pain while you are awake
• alcohol
• aspirin for pain relief or to thin your blood.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast feeding, ask your doctor or pharmacist for advice before taking any medicine.
Folic Acid tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

How to take Folic Acid tablets
Always take Folic Acid tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with water.

Doses:
Adults (including the elderly):
• To treat folate deficiency anaemia: 5mg a day for 4 months, which may be increased up to a maximum of 15mg a day.
• To prevent folate deficiency caused by some medicines: 5mg a day for 4 months, which may be increased up to a maximum of 15mg a day.
• To prevent folate deficiency caused by long-term red blood cell damage or kidney dialysis: 5mg every 1-7 days.
• To prevent neural tube defects in babies, where women are at risk of having an affected child: 5mg a day started before conception and continued throughout the first three months.
• To prevent folate deficiency during pregnancy: 5mg a day continued to birth.

Use in children and adolescents:
For young children a more suitable form of the medicine should be used.
• To treat folate deficiency anaemia: Children 1-18 years old: 5mg a day for 4 months. The maintenance dose is 5mg every 1-7 days.
• To treat haemolytic anaemia and metabolic disorders: Children 1-12 years old: 2.5mg-5mg once a day. Children 12-18 years old: 5-10mg once a day.
• To prevent folate deficiency in kidney dialysis: Children 1-12 years old: 250micrograms per kg of body weight (up to a maximum of 10mg) once a day. Children 12-18 years old: 5-10mg once a day.

If you take more than you should
If you (or someone else) swallow a lot of the tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take the tablets
If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

Possible side effects
Like all medicines, Folic Acid tablets can cause side effects, although not everybody gets them.
Tell your doctor if you notice any of the following side effects, they get worse or you notice any not listed:

Rare (may affect up to 1 in 1,000 people)
• Allergic reaction (hypersensitivity) e.g. itchy/red skin, rash.
• Severe allergic reaction (anaphylactic reaction) – swelling of the face, lips, tongue or throat or difficulty breathing or swallowing, shock (cold sweaty skin, weak pulse, dry mouth, dilated pupils).
• Stomach and intestines: loss of appetite, feeling sick, a bloated feeling, wind.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

How to store Folic Acid tablets
Keep out of the sight and reach of children. Store below 25°C in a dry place.

Protect from light.
Do not use Folic Acid tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Contents of the pack and other information
What Folic Acid tablets contain
• The active substance (the ingredient that makes the tablets work) is folic acid PhEur. Each tablet contains 5mg of the active substance.
• The other ingredients are colloidal silica, lactose, maize starch, magnesium stearate, E460.

What Folic Acid tablets look like and contents of the pack
Folic Acid tablets are yellow, circular, biconvex, uncoated tablets.

Pack size is 28.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in November 2018

If you would like a leaflet with larger text, please contact 01271 385257.

Actavis, Barnstaple, EX32 8NS, UK

Folic Acid 5mg 28 tablets PIL - UK

Item number: BBBA3496

Dimensions: 148x210 (Reel Fed)

Supplier: Actavis UK

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FMD info

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Version 2
01.11.2017

Actavis, Barnstaple, EX32 8NS, UK

Folic Acid Tablets 5mg x 28's (UK)

JDE No.: 50957880

Dimensions: 148x210 (Reel Fed)
Component: Leaflet for Blister
Pharmacode: 4315

Date Sent: 14/09/18
Technologist: R.Wrey

Technically Approved