

## **Package leaflet: Information for the user**

### **Folic acid Colonis 1 mg/ml oral solution** Folic acid

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Folic acid oral solution is and what it is used for
2. What you need to know before you take Folic acid oral solution
3. How to take Folic acid oral solution
4. Possible side effects
5. How to store Folic acid oral solution
6. Contents of the pack and other information

#### **1. What Folic acid oral solution is and what it is used for**

This medicine is called Folic acid Colonis 1mg/ml Oral Solution (referred to in this leaflet as Folic acid oral solution). It contains folic acid (vitamin B9), which belongs to a group of vitamins called 'B vitamins'. Each 1ml contains 1mg of folic acid.

Folic acid oral solution is used for the prevention and treatment of conditions caused by deficiency of folic acid:

1. Prevention of neural tube defects (abnormalities of the spine, eg. spina bifida) in babies, including if you have previously had a baby with this disorder.
2. Prevention and treatment of anaemia caused by folic acid deficiency. This may occur in the following situations:

- pregnancy
- excessive alcohol intake or poor nutrition
- effects of other drugs (eg. anticonvulsants, used to prevent fits)
- sickle cell anaemia (or other types of anaemia caused by abnormal red blood cells)
- problems with absorption of folic acid from the gut (e.g. tropical sprue or coeliac disease).

#### **2. What you need to know before you take Folic acid oral solution**

##### **Do not take Folic acid oral solution:**

- if you are **allergic** (hypersensitive) to folic acid or any of the other ingredients in this liquid (see section 6)
- if you display signs of an allergic reaction such as a **rash, itching** or **breathing** problems

- if you have a **tumour** or **cancer**.

If any of the above apply to you, **do not take this medicine** and **talk** to your **doctor**.

## Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if:

- you have been told that you have something called ‘**pernicious anaemia**’ or ‘**vitamin B12 deficiency**’
- you are having **haemodialysis**.

## Children and adolescents

Folic acid oral solution is not suitable for use in infants under the age of 1 years old.

## Other medicines and Folic acid oral solution

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines you have bought without a prescription, including herbal medicines. This is because either Folic acid oral solution affects the way some other medicines work, or some medicines can affect the way Folic acid oral solution works.

In particular, **tell your doctor** if you are taking **any of the following**:

- antiepileptics (used to treat **epilepsy and fits**) such as phenytoin, phenobarbital and primidone
- **antibiotics** (used to treat **infections**) such as chloramphenicol and co-trimoxazole. This is because antibiotics may affect the way Folic acid oral solution works.
- **sulfasalazine**, a medicine known as an immunosuppressant (used to treat **ulcerative colitis, Crohn’s disease** or **rheumatoid arthritis**)
- **methotrexate** (used to treat **Crohn’s disease, rheumatoid arthritis** or **cancer**).

## Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

### Pregnancy

- Folic acid supplements are often necessary in pregnancy. There are no known risks in using them unless the points listed above in section 2 apply to you. If these apply to you **talk to your doctor before** you take this medicine.

### Breast-feeding

- Folic acid is passed into breast milk. However, no adverse effects have been observed in breast fed infants whose mothers were receiving folic acid.

### Fertility

- There are no known risks to fertility from the use of folic acid.

## Driving and using machines

Folic acid oral solution is not likely to affect your ability to drive or use any tools or machines.

**Other precautions you should take**

If you see another doctor or go into hospital, let them know what medicines you are taking.

**Folic acid oral solution contains sodium methyl parahydroxybenzoate (E219)**

This medicine contains sodium methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed).

**3. How to take Folic acid oral solution**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is for **oral use only**.

**Dose: Adults and Elderly people****To treat folate deficiency anaemia:**

The recommended dose is 5ml a day for 4 months, which may be increased up to a maximum of 15ml a day.

**To prevent folate deficiency caused by some medicines:**

The recommended dose is 5ml a day for 4 months, which may be increased up to a maximum of 15ml a day.

**To prevent folate deficiency caused by long-term red blood cell damage or kidney dialysis:**

The recommended dose can vary from a minimum of 5ml every week to a maximum of 5ml every day. Your doctor will tell you what dose you should take.

**To prevent neural tube defects in babies, in women who have previously had an affected child:**

The recommended dose is 5ml a day started before conception and continued throughout the first three months of pregnancy.

**To prevent neural tube defects in babies, in women who are at a lower risk of having an affected child:**

The recommended dose is 0.4ml a day started before conception and continued throughout the first three months of pregnancy.

**Dose: Pregnancy**

The recommended dose during pregnancy is 5ml a day, continued until birth in women who have previously had an affected child and 0.4ml per day in women who are at lower risk of having an affected child.

**Dose: Children**

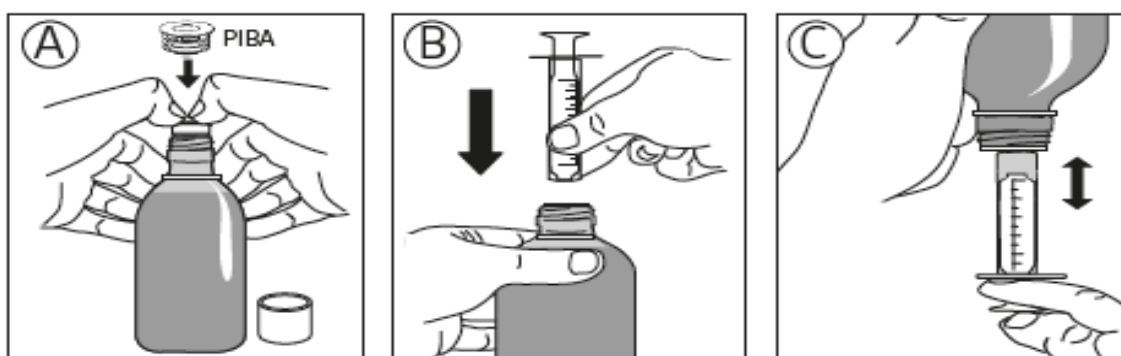
The usual dose is 5 to 10ml a day.

Your doctor will decide the correct dose for you, and will advise you how long to take your medicine for.

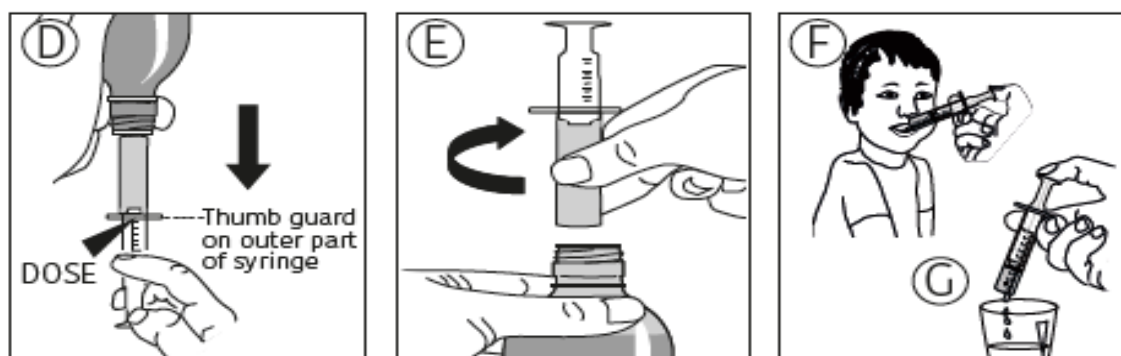
**Directions for use**

This medicine should be taken by mouth using the graduated oral syringe and Press-In Bottle Adaptor (PIBA) provided with the product.

1. Open the bottle by pressing down on the child resistant cap very firmly and turning it anticlockwise.
2. Insert the syringe adaptor (PIBA) into the bottle neck and press it down very firmly into the bottle neck to make sure that it fits well enough to avoid any spillages (figure A).
3. Take the syringe and push it firmly into the adaptor opening (figure B).
4. Turn the bottle upside down and fill the syringe with a small amount of solution by pulling the plunger down (figure C).
5. Then push the plunger fully back up to remove any possible bubbles (figure C).



6. Finally, pull the plunger down until the thumb guard is lined up with the graduation mark for the required ml dose/measure (figure D).
7. Turn the bottle the right way up and remove the syringe from the adaptor (figure E).
8. Put the end of the syringe into your mouth and push the plunger slowly back in to take the medicine (figure F).
9. Repeat steps 3 to 6 if necessary to take the full dose prescribed by your doctor.
10. Wash the syringe with water and let it dry before you use it again (figure G).



11. Leaving the adaptor in the bottle neck, screw the plastic cap back onto the bottle.

### **If you take more Folic acid oral solution than you should**

There have been no cases of people taking an overdose with this medicine, even extremely high doses are unlikely to cause harm to patients. However, if you think you have taken more than you should, talk to your doctor or go to a hospital straight away.

### **If you forget to take Folic acid oral solution**

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do **not** take a **double dose** (two doses at the same time) to make up for a forgotten dose.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, Folic acid oral solution can cause side effects although not everybody gets them.

### **Tell your doctor if you get any of these rare side effects (may affect up to 1 in 1,000 people):**

- Loss of appetite, feeling sick (nausea), being sick (vomiting) or an upset stomach
- Allergic reactions such as erythema (red skin rash), rash, itching, urticaria (itchy skin rash), difficulty in breathing and anaphylactic shock (swelling of the face, lips, tongue, throat, severe wheezing).

### **If you have an allergic reaction to Folic acid oral solution see a doctor straight away.**

#### Reporting of suspected side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the relevant medicines authority (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

The Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **5. How to store Folic acid oral solution**

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Keep the bottle in the outer carton.
- After first opening do not store above 25°C.
- Once this bottle has been opened use within 3 months.
- Do not use this medicine after the expiry date which is stated on the label after Exp:
- The expiry date refers to the last day of that month.
- Do not use Folic acid oral solution if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Folic acid oral solution contains**

- The active ingredient is folic acid. Each 1ml oral solution contains 1mg folic acid.
- The other ingredients are:
  - Sodium Methyl Parahydroxybenzoate (E219), see section 2
  - Disodium Edetate (E385)
  - Mannitol (E421)
  - Hydrochloric Acid, Concentrated (E507)
  - Water, Purified

### **What Folic oral solution looks like and contents of the pack**

Folic acid oral solution 1mg/ml is a clear, yellow and odourless solution supplied in a 150ml amber glass bottle with child-resistant cap.

A 5ml graduated oral dosing syringe and a “press-in” syringe/bottle adaptor (PIBA) are also supplied in the carton.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Colonis Pharma Limited  
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 Bloomsbury  
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 WC1B 3HH  
 United Kingdom

#### **Manufacturer**

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