

## Package leaflet: Information for the user

### Clonfolic 0.4 mg Tablets

Folic Acid

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

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

1. What Clonfolic 0.4 mg Tablets are and what they are used for
2. What you need to know before taking Clonfolic 0.4 mg Tablets
3. How to take Clonfolic 0.4 mg Tablets
4. Possible side effects
5. How to store Clonfolic 0.4 mg Tablets
6. Contents of the pack and other information

#### **1. WHAT CLONFOLIC 0.4 mg TABLETS ARE AND WHAT THEY ARE USED FOR**

The name of your medicine is Clonfolic 0.4 mg Tablets. It contains folic acid which belongs to a group of vitamins called 'B vitamins'. It is essential for good health. Folic acid is required for the manufacture of nucleic acids-the genetic material of cells. It is vital for the development and proper function of the central nervous system.

Clonfolic is indicated for the prevention of first time neural tube defects\* (including Spina Bifida) in the foetus. The neural tube is part of the nervous system and is located within the spine. Neural tube defects cause stillbirth, neonatal death and severe disabilities such as Spina Bifida. Clonfolic is indicated for use by all females who are capable of conceiving, whether planning to do so or not. For advice on dosing when planning a pregnancy and in the first trimester of pregnancy see Section 3.

\* Studies have shown that over 70% of first time neural tube defects such as Spina Bifida can be prevented by taking folic acid (0.4mg) daily.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CLONFOLIC 0.4 mg TABLETS**

##### **Do not take Clonfolic 0.4 mg Tablets:**

- If you are allergic (hypersensitive) to folic acid or any of the other ingredients. Signs of an allergic reaction include a rash, itching or shortness of breath.
- If you have a deficiency of vitamin B<sub>12</sub> possibly caused by pernicious anaemia or a vegetarian diet.

##### **Warning and Precautions**

##### **Talk to your doctor or pharmacist before taking Clonfolic 0.4 mg Tablets**

- If you are under therapy for a folate-dependent tumour.
- If you have a family history of neural tube defects (NTDs), as you may need a higher dose of folic acid than this product provides.
- If you previously gave birth to a baby with a neural tube defect (NTD)
- If you suffer from diabetes, as you may need a higher dose of folic acid than this product provides.
- If you are obese, as you may need a higher dose of folic acid than this product provides.

##### **Other medicines and Clonfolic 0.4mg Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- Anti-epileptics (medicines used to treat epilepsy and fits) such as phenytoin, phenobarbital or primidone. Your doctor may need to change the amount of anti-epileptic medicine you are taking, because folic acid tablets may reduce the effect of these medicines.
- Antibacterials (used to treat infections) e.g. chloramphenicol and co-trimoxazole.
- Sulfasalazine, an anti-inflammatory drug used for the treatment of arthritis or inflammatory bowel disease, including ulcerative colitis or Crohn's disease.
- Methotrexate, a disease modifying anti-rheumatic drug used to treat severe active rheumatoid arthritis, severe psoriasis and certain types of cancer.

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. Folic acid is indicated for use during pregnancy and lactation.

### **Driving and using machines**

Clonfolic 0.4 mg Tablets are not likely to affect you being able to drive or use any tools or machines.

### **Clonfolic 0.4 mg Tablets contain Lactose Monohydrate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE CLONFOLIC 0.4 mg TABLETS**

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

The recommended dose is

### **Adult females**

All females who are capable of conceiving should take **one tablet (0.4 mg) daily**. If you are planning a pregnancy you should begin taking Clonfolic at least **14 weeks** before you become pregnant and continue taking it for at least the first **12 weeks** of pregnancy.

The tablets should be swallowed with water.

### **If you take more Clonfolic 0.4 mg Tablets than you should**

If you take too many tablets you should contact your doctor, however large doses of folic acid are unlikely to cause harm.

### **If you forget to take Clonfolic 0.4 mg Tablets**

Take one as soon as you remember and continue as before. Do not take a double dose 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, this medicine can cause side effects although not everybody gets them.

### **If you have an allergic reaction to Clonfolic 0.4 mg Tablets see a doctor straight away**

An allergic reaction may include:

- Any kind of skin rash, flaking skin, boils or sore lips and mouth
- Sudden wheezing, fluttering or tightness of the chest or collapse.

### **Tell your doctor if you get any of these side effects:**

- Feeling sick (nausea)
- Being sick (vomiting)
- Upset stomach

Severe allergic reaction (anaphylactic reaction): frequency not known.

### **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 HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE CLONFOLIC 0.4 mg TABLETS**

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Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and outer carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect the tablets from moisture.

Keep blister in the outer carton in order to protect the tablets from light.

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 protect the environment.

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

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#### **What Clonfolic 0.4 mg Tablets contain**

- The active substance is folic acid. Each tablet contains 0.4 mg (400 micrograms) folic acid.
- The other ingredients are lactose monohydrate, maize starch, pregelatinised starch and magnesium stearate.

#### **What Clonfolic 0.4 mg Tablets look like and contents of the pack**

Clonfolic 0.4 mg Tablets are pale yellow, circular biconvex tablets.

Pack sizes: 28, 56, 84 and 98 tablets.

Not all pack sizes may be marketed.

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

##### **Marketing Authorisation Holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

##### **Manufacturer**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland  
STADA M&D SRL, Str. Trascăului, nr 10, RO-401135, Turda, Romania

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## Some important questions on Spina Bifida and Clonfolic

- **What is Spina Bifida**

Spina Bifida is a birth defect of the back bone and sometimes, much more importantly, the spinal cord. It is one of a group of birth defects, called neural tube defects, that affect the spine and brain. The neural tube is the embryonic structure that develops into the brain and spine.

- **How common is Spina Bifida?**

Spina Bifida is one of, if not the most common severe birth defect in this country affecting up to 100 babies (2 per week) in Ireland annually.

- **How does Spina Bifida affect a child?**

Every unborn infant's spine is open when it first forms, but it normally closes by the 29th day following conception. In Spina Bifida, the backbone never closes completely, leading to varying degrees of malformation, leg paralyses, bladder and bowel control problems.

- **Can Spina Bifida be prevented?**

\*Clinical studies now show that over 70% of Spina Bifida and other neural tube defects can be prevented by taking folic acid (Clonfolic).

- **What is folic acid? (Clonfolic)**

Folic acid is a member of the Vitamin B group. It is required for the manufacture of nucleic acid - such as DNA – the genetic material of cells.

- **Who should take folic acid? (Clonfolic)**

Clonfolic is indicated for use by all females who are capable of conceiving, whether planning to do so or not. For advice on dosing when planning a pregnancy and in the first trimester of pregnancy see Section 3.

- **How much should I take?**

All females who are capable of conceiving should take one tablet (0.4 mg) daily – this is the exact amount in one tablet of Clonfolic.

- **When should I start if I am planning a pregnancy?**

Studies show that you should start taking one Clonfolic tablet daily at least **14 weeks** before conception to allow adequate levels of folic acid to build up in your body.

- **How long should I continue to take folic acid? (Clonfolic)**

You should continue taking it for at least the first **12 weeks** of pregnancy.

- **Do I need Clonfolic if I have a good diet?**

Even though folic acid occurs naturally in many vegetables, studies now show that it is not possible to get sufficient folic acid from the diet to prevent first time neural tube defects (such as Spina Bifida) in the foetus.

FOR THE PREVENTION OF SPINA BIFIDA  
and other neural tube defects\*