

Lexpec[®] 2.5mg/5ml Oral Solution folic acid

- Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.



If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. What Lexpec is and what it is used for

The name of your medicine is Lexpec 2.5mg/5ml Oral Solution (called Lexpec in this leaflet). It contains folic acid. This belongs to a group of vitamins called 'B vitamins'.

Lexpec is used for the following:

- Anaemia which can be caused by:
 - a lack of vitamins in adults and children
 - pregnancy
 - an addiction to alcohol
 - a medicine that is used to control fits
- Sickle Cell Anaemia or other anaemias caused by a lack of red blood cells
- Illnesses called 'Tropical and Non-tropical Sprue'. In these illnesses parts of your food cannot be absorbed by the gut
- Coeliac disease. This is an illness where your body cannot digest gluten.

2. What do you need to know before you take Lexpec

Do not take Lexpec and tell your doctor if:

 You are allergic (hypersensitive) to folic acid or any of the other ingredients in this liquid (listed in Section 6 below)

Signs of an allergic reaction include a rash, itching or shortness of breath

■ You have a tumour or cancer

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

Continued overleaf

Take special care with Lexpec

Before you take Lexpec, tell your doctor if:

You have been told that you have something called 'pernicious anaemia' or a 'vitamin B12 deficiency'.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Lexpec can affect the way some other medicines work. Also, some medicines can affect the way Lexpec works.

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

- antiepileptics (to treat epilepsy and fits) such as phenytoin, phenobarbital and primidone. Your doctor may need to change the amount you are taking. This is because Lexpec may make these medicines work less well
- antibacterials (to treat infections) such as chloramphenicol and co-trimoxazole
- sulfasalazine (to treat ulcerative colitis, Crohn's disease or rheumatoid arthritis)
- methotrexate (to treat Crohn's disease, rheumatoid arthritis or cancer).

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding. If you are a woman and you are pregnant, this medicine is unlikely to cause any harm to you or your unborn child.

Driving and using machines

Lexpec is not likely to affect you being able to drive or use any tools or machines.

Important information about what is in Lexpec

This medicine contains:

- Methyl, ethyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may happen some time after starting the medicine.
- Propylene glycol (E1520). This medicine contains 14.5 mg propylene glycol in each 5ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
- Sodium. This medicine contains 10.4 mg sodium (main component of cooking/table salt) in each 5ml. This is equivalent to 0.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Lexpec

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure.

Taking this medicine

- This medicine contains 2.5mg of folic acid in each 5ml
- Take this medicine by mouth

Adults and older people

The usual dose for adults and older people is:

- 10mg (20ml) to 20mg (40ml) each day
- You can split this daily dose into smaller doses which you can take through the day You will usually take this medicine for 14 days.
- However, your doctor may decide that you should take this medicine for longer. If this is the case, then the usual dose will be 2.5mg (5ml) to 10mg (20ml) each day.

Pregnancy

 If you are taking this because you are pregnant, your dose will be 0.5mg (1ml) a day.

Children

The usual dose for children is:

- 5mg (10ml) to 15mg (30ml) each day
- You can split this daily dose into smaller doses which you can take through the day

If you take more Lexpec than you should

There have been no cases of people taking an overdose with this medicine. 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 Lexpec

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, Lexpec can cause side effects although not everybody gets them.

If you have an allergic reaction to Lexpec 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.

Frequency not known: severe allergic reaction (anaphylactic reaction).

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

Feeling sick (nausea), being sick (vomiting) or an upset stomach.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Lexpec

- Keep out of the sight and reach of children
- Do not store above 25°C
- Do not use after the expiry date which is stated on the label and carton (Exp: month, year)
- The expiry date refers to the last day of that month
- Do not use Lexpec if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist
- 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

6. Contents of the pack and other information

What Lexpec contains

- The active substance is folic acid.
- The other ingredients are mannitol (E421), glycerol (E422), methyl hydroxybenzoate (E218), ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216), sodium dihydrogen phosphate, disodium hydrogen phosphate (E339), strawberry flavour (containing propylene glycol (E1520)), di-sodiumethylenediamine tetra acetic acid and purified water

What Lexpec looks like and contents of the pack

A pale yellow liquid with an odour of strawberry. It comes in a brown glass bottle holding 150ml of solution.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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