

DBL™ Leucovorin Calcium Injection and Tablets

Leucovorin Calcium USP (loo-koe-VOR-in) (also called Calcium Folate or Folinic Acid)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions that you may have about DBL™ Leucovorin Calcium Injection and DBL™ Leucovorin Calcium Tablets (leucovorin calcium). It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with leucovorin calcium, against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

What DBL™ Leucovorin Calcium is used for

DBL™ Leucovorin Calcium is considered to be a supportive therapy. It is used in two main situations:

1. When your body does not have enough folic acid.
This occurs in conditions such as megaloblastic anaemia, where the level of red blood cells and iron in the blood is too low. Megaloblastic anaemia can happen during pregnancy or infancy, or due to liver disease, malnutrition, or a reduced ability to absorb folic acid from the diet.
2. As an antidote or rescue therapy to the toxic effects of some medications such as methotrexate.

DBL™ Leucovorin calcium is not addictive.

Before you are given DBL™ Leucovorin Calcium

When you must not be given it

You must not be given DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin Calcium Tablets if you have or have had an allergy to leucovorin calcium, folic acid, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to leucovorin calcium may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You must not be given DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin Calcium Tablets if you have pernicious anaemia or any other megaloblastic anaemias which are due to a lack of Vitamin B12

You must not be given DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin Calcium Tablets after the expiry date (EXP) printed on the pack.

If you are given this medicine after the expiry date has passed, it may not work as well.

You must not be given DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin

Calcium Tablets if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin Calcium Tablets, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of being given leucovorin calcium when breastfeeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- pernicious anaemia
- Vitamin B12 deficiency
- fits or convulsions (epilepsy).

If you have not told your doctor or pharmacist about any of the above, tell them before you are given leucovorin calcium.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and leucovorin calcium may interfere with each other. These include:

- some drugs used to treat epilepsy (fits), including phenytoin, phenobarbitone and primidone
- fluorouracil (5-FU), a medicine used to treat some cancers
- folic acid antagonists, medicines used to treat some infections (eg cotrimoxazole or pyrimethamine)
- methotrexate, a medicine used to treat rheumatoid arthritis, psoriasis, inflammatory bowel disease or some cancers

These medicines may be affected by leucovorin calcium, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

How DBL™ Leucovorin Calcium is given

How much is given

Your doctor will decide what dose and how long you will receive leucovorin calcium. This depends on the condition you are being treated for.

How it is given

DBL™ Leucovorin Calcium Injection can be given in three ways:

- as a slow injection into a vein
- as a continuous infusion (intravenous drip) into a vein
- as a deep injection into a large muscle.

DBL™ Leucovorin Calcium Injection must only be given by a doctor or nurse.

DBL™ Leucovorin Calcium Tablets should be swallowed with a full glass of water.

DBL™ Leucovorin Calcium Tablets should be taken on an empty stomach, for example, at least half an hour before food or two hours after food.

If you take too much (overdose)

As DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin Calcium Tablets are given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin Calcium Tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of a leucovorin calcium overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While you are being given DBL™ Leucovorin Calcium

Things you must do

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin Calcium Tablets.

Tell all the doctors, dentists and pharmacists who are treating you that you are being given leucovorin calcium.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Leucovorin Calcium.

Things you must not do

Do not give leucovorin calcium to anyone else, even if they have the same condition as you.

Do not take leucovorin calcium to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking leucovorin calcium, or lower the dosage, without checking with your doctor or pharmacist.

Side effects

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given leucovorin calcium.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- fever
- nausea, vomiting
- diarrhoea
- sore mouth / mouth ulcers or cold sores
- irritability or trouble sleeping

These side effects are usually mild.

Tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:

- signs of an allergic reaction, such as those listed at the start of this leaflet.
- fits or convulsions.
- Stomach pain

These are serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of side effects.

You may not experience any of them.

Even after you have finished being treated with DBL™ Leucovorin Calcium, you should tell your doctor if you notice any side effects listed in this section.

After being given leucovorin calcium

Storage

DBL™ Leucovorin Calcium Injection will be stored in the pharmacy or on the ward.

The injections should be kept in a refrigerator where the temperature stays between 2 - 8 degrees C, and protected from light.

DBL™ Leucovorin Calcium Tablets should be kept in a cool dry place where the temperature stays below 25 degrees C.

Do not store DBL™ Leucovorin Calcium Tablets or any other medicine in the bathroom or near a sink.

Do not leave them in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep DBL™ Leucovorin Calcium Tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using DBL™ Leucovorin Calcium Injection or DBL™ Leucovorin Calcium Tablets or they have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

DBL™ Leucovorin Calcium Injection

What it looks like

DBL™ Leucovorin Calcium Injection is a clear, straw-coloured solution.

Ingredients

Active ingredient:

- calcium folinate

Other ingredients:

- sodium chloride

- water for injection

DBL™ Leucovorin Calcium Tablets

What they look like

DBL™ Leucovorin Calcium tablets are yellowish-white, round, flat tablets. They are scored and engraved with the letters CF.

Ingredients

Active ingredient:

- calcium folinate, equivalent to 15 mg folinic acid

Other ingredients:

- lactose
- microcrystalline cellulose
- magnesium stearate

DBL™ Leucovorin Calcium Tablets do not contain sucrose, gluten, tartrazine, or any other azo dyes.

Sponsor

DBL™ Leucovorin Calcium Injection and DBL™ Leucovorin Calcium Tablets are supplied by:

Australian Sponsor

Hospira Australia Pty Ltd
 ABN 58 097 064 330
 Level 3
 500 Collins Street
 Melbourne VIC 3000
 Australia

New Zealand Sponsor

Hospira NZ Limited
 58 Richard Pearse Drive
 Airport Oaks, Mangere 2022
 Auckland
 New Zealand

Australian Registration Numbers:

DBL™ Leucovorin Calcium Injection

- 15 mg/2 mL ampoule
AUST R 16351
- 50 mg/5 mL vial
AUST R 42148
- 300 mg/30 mL vial
AUST R 116688

DBL™ Leucovorin Calcium Tablets

- 15 mg AUST R 16364

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21st June 2016.