

FLUDARABINE EBewe

Fludarabine Phosphate

Consumer Medicine Information

What is in this leaflet

This leaflet provides a summary of some of the important things you need to know about this medicine. It does not contain all available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you receiving Fludarabine Ebewe against the benefits they expect it will have for you. Only your doctor is able to weigh up all the relevant facts and you should consult him/her about all aspects of this medication as it relates to you.

If you have any concerns about receiving Fludarabine Ebewe, ask your doctor.

Keep this leaflet. You may need to read it again.

It is important to remember that Fludarabine Ebewe is a **PRESCRIPTION ONLY MEDICINE**.

Fludarabine Ebewe will only be given to you by specially trained personnel in a hospital environment.

What Fludarabine Ebewe is used for

Fludarabine Ebewe is used to treat a form of leukaemia known as chronic lymphocytic leukaemia, or CLL. All cells in the body produce new cells like themselves by dividing. For this purpose, the cells genetic material (DNA) must be copied and reproduced. Fludarabine Ebewe works by hindering the production of new DNA. Therefore, when Fludarabine Ebewe is taken up by the cancer cells it stops the growth of new cancer cells. It has been discovered that Fludarabine Ebewe works especially well against some cancers of the white blood cells.

Fludarabine Ebewe may have been prescribed for another reason. Ask your doctor if you have any questions about why Fludarabine Ebewe has been prescribed for you.

Before you are given Fludarabine Ebewe

This medicine should not be given to you if:

- **You are pregnant or intend to become pregnant.**

This medicine is not recommended during pregnancy.

- **You are breast-feeding or plan to breast feed.**

This medicine is not recommended while you are breast-feeding.

- **Your kidney function is severely reduced**
- **The number of red blood cells is reduced due to a breaking down of these cells (haemolytic anaemia)**
- **You have an allergic or unusual reaction previously to fludarabine phosphate or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include rashes, itching and redness of the skin and swelling of the tongue or face.

The effects of Fludarabine Ebewe have not been studied in children.

If your liver does not work properly, you have a poor state of health or if you are over 75 years old, Fludarabine Ebewe will be given with caution.

If you are not sure whether any of these apply to you, check with your doctor or pharmacist.

Things to be careful of:

Be careful driving or operating machinery until you know how Fludarabine Ebewe affects you.

Fludarabine Ebewe may reduce your ability to drive or use machines, since tiredness, weakness and visual disturbances have been observed. Patients experiencing such adverse effects should avoid driving and using machines.

Before you are given Fludarabine Ebewe, tell your doctor if:

You have or have had any other medical conditions, especially the following:

- **Kidney problems**
- **Anaemia**
- **You are taking other medicines.**

Fludarabine Ebewe should not be used together with the leukaemia drug pentostatin.

If it is found that your kidneys do not work properly you may be given this medicine at a reduced dose.

The effectiveness of Fludarabine Ebewe may be reduced by medications containing dipyridamole and similar substances.

During and after treatment with Fludarabine Ebewe, vaccination with live vaccines should be avoided.

Men, and women who may still be fertile, must use a reliable form of contraception during and for at least 6 months after stopping treatment.

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

Some medicines may interfere with Fludarabine Ebewe and some may cause unwanted side effects if taken while you are on Fludarabine Ebewe treatment.

This is especially true if you are on any other medicines with similar side effects as Fludarabine Ebewe. In some cases, two different medicines may be used together by your doctor even if an interaction might occur. In these cases,

your doctor may change your dose

If you are in doubt, check with your doctor.

How Fludarabine Ebewe is given

How it is given

Fludarabine Ebewe must only be given by a doctor or nurse.

Fludarabine Ebewe is injected into a vein (often in the arm) once each day for 5 consecutive days. This 5 day course is then repeated once every 28 days.

How much is given

The dosage of Fludarabine Ebewe that is correct for you will be exactly worked out by your specialist.

Because of the complexity of CLL and the possible side effects of Fludarabine Ebewe, it should only be prescribed by specialist doctors with experience with similar medications.

If you have any concerns about the dosage you receive, ask your doctor.

In Case of Overdose

Your doctor will decide what dose of Fludarabine Ebewe you need, and this will be administered in the clinic or hospital under close supervision from nursing and medical staff. The dose is determined by your weight and height. The risk of overdose in these circumstances is low. In the event of overdose occurring, your doctor will stop the therapy and decide on the necessary treatment.

While you are being given Fludarabine Ebewe

Things you MUST do:

- Be sure to keep all of your doctors appointments so that your progress can be checked.
- If you become pregnant while under Fludarabine Ebewe treatment, tell your doctor immediately

Things you MUST NOT do:

- Take any additional medicines without the advice of your doctor or pharmacist.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are being given Fludarabine Ebewe.

Any medicine may cause some unwanted side effects, including Fludarabine Ebewe. Sometimes they are serious, most of the time they are not. Side effects can sometimes be prevented or minimised by blood and urine tests as well as taking into account your overall physical condition.

Ask your doctor to answer any questions that you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor immediately if you notice any of the following:

The following are uncommon or rare effects. You may need urgent medical attention.

- If you experience any difficulty in breathing or have a cough tell your doctor immediately. An allergic reaction in the lungs, symptoms of which are difficulties in breathing and coughing, is a rare effect.
- Unusual bruising
- Excessive bleeding after injury
- Signs of infection (e.g. fever, chills, feeling unwell, pain)
- Difficulty moving, speaking or seeing
- Agitation
- Confusion
- Pain in your side
- Blood in your urine
- Dark, tarry stools or stools containing blood
- Neurological disorders manifested by headache, feeling sick (nausea) and vomiting, seizures, visual disturbances including vision loss, changes in mental status (thinking abnormal, confusion, altered consciousness), and occasionally neuromuscular disorders manifested by muscle weakness in your limbs (including irreversible partial or complete paralysis) (symptoms of leukoencephalopathy, acute toxic leukoencephalopathy or posterior reversible leukoencephalopathy syndrome (RPLS))

Sever blisters, or bleeding in the lips, eyes, nose, mouth or genitals.

When used in patients with acute leukemia at doses four times greater than the recommended dose for CLL, a third of patients experienced severe central nervous system effects including blindness, coma and death.

In rare cases heart failure, irregular heart beat and skin cancer have been reported in patients treated with Fludarabine Ebewe.

The following are the more common side effects of Fludarabine Ebewe and are usually mild.

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

- Generally feeling unwell
- Nausea and vomiting. This medicine can cause nausea and vomiting. If symptoms are severe or persistent you should contact your doctor or clinic.
- Tiredness.
- Loss of appetite.
- Weakness
- Numb or weak arms or legs
- Swelling in your hands feet or ankles
- Problems with your eyesight
- Inflammation of the lining of the mouth
- Skin rashes

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor. Some side effects may only be seen by your doctor.

Storage

Fludarabine Ebewe will be stored appropriately at the pharmacy or on the ward. The injection is kept in a refrigerator where the temperature stays between 2°C and 8°C.

Product Description

What it looks like

Fludarabine Ebewe is a clear, colourless to almost colourless solution, in a clear glass vial.

Fludarabine Ebewe can be identified by an Australian Register Number, which is found on the packaging:

AUST R 135540
Fludarabine Ebewe 50mg in 2mL glass vial (packs of 1 vial, 5 vials, and 10 vials).

Ingredients

Fludarabine Ebewe contains fludarabine phosphate 25mg/mL, dibasic sodium phosphate dihydrate, sodium hydroxide, in water for injections.

Manufacturer

Fludarabine Ebewe is made by: EBEWE Pharma Ges.m.b.H. Nfg. KG
A-4866 Unterach
Austria

Sponsor

Fludarabine Ebewe is distributed in Australia by: Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park
Australia
Tel: 1800 634 500

Fludarabine Ebewe is distributed in New Zealand by: Novartis New Zealand Ltd
PO Box 99102
Newmarket
Auckland 1149
Tel: 0800 354 335

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