Fludarabine ACT

fludarabine phosphate 50 mg powder for injection vial

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Fludarabine ACT. It does not contain all of the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of using Fludarabine ACT against the benefits it is expected to 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 using Fludarabine ACT, ask your doctor.

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

What Fludarabine ACT is used for and how it works

Fludarabine ACT 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 ACT works by hindering the production of new DNA. Therefore, when Fludarabine ACT is taken up by the cancer cells it stops the growth of new cancer cells. It has been discovered that Fludarabine ACT works especially well against some cancers of the white blood cells.

Before you are given Fludarabine ACT

When you must not use it

You must not be given Fludarabine ACT if any of the following apply to you:

- Pregnancy or breast-feeding
- Allergy (hypersensitivity) to any of the ingredients of this medicine
- Your kidney function is severely reduced
- The number of red blood cells is reduced due to a breaking down of these cells (hemolytic anemia)

The effects of Fludarabine ACT have not been studied in children. It should not be used together with the leukaemia drug pentostatin.

Before you use it

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

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

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.

Check with your doctor about any vaccinations you may need, because live vaccinations should be avoided during and after treatment with Fludarabine ACT.

It is not known whether Fludarabine ACT decreases your fertility.

Fludarabine ACT 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.

While using Fludarabine ACT

When used in patients with acute leukemia at doses four times greater than the recommended dose for chronic lymphocytic leukemia (CLL), a third of patients experienced severe central nervous system effects including blindness, coma and death. Such effects have only rarely (coma and agitation) or uncommonly (confusion) been reported in patients who receive the recommended dose for CLL. However, you should mention to your doctor any unusual symptoms. The effect of long-term use of Fludarabine ACT on the central nervous system is unknown.

The number of normal blood cells may also be reduced for periods of up to 12 months duration. You will have regular blood tests during treatment. On some occasions death has been reported in patients experiencing reductions in the number of normal blood cells.

Special regular checkups will be necessary in case you are over 75 years old, or your liver or kidneys do not work properly.

If you need a blood transfusion and you are being (or have been) treated with Fludarabine ACT, you should mention this to the doctor.

If your disease is very severe, your body may not be able to get rid of all the waste products from the cells destroyed by Fludarabine ACT. This may cause dehydration, kidney failure and heart problems. Your doctor will be aware of this and may give you other drugs to stop this happening.

The worsening or flare up of pre-existing skin cancer as well as new onset of skin cancer has been reported in patients during or after Fludarabine ACT therapy.

Taking other medicines

This medicine should not be used with another drug called pentostatin (deoxycoformycin).

The effectiveness of Fludarabine ACT may be reduced by medications containing dipyridamole and similar substances. If you are taking any other medicines regularly, including medicines bought from a supermarket, health food store or pharmacy, tell your doctor.

How Fludarabine ACT is given

How much is given

The dose of Fludarabine ACT is calculated according to your body surface, which is calculated from your weight and height.

The recommended dose is 25 mg fludarabine phosphate/m^2 body surface given daily for 5 consecutive days every 28 days by the intravenous route.

How it is given

Fludarabine ACT is given as a 5 day treatment course which is repeated each month. The treatment involves injecting Fludarabine ACT into a vein (often in the arm) once each day for 5 consecutive days. Your specialist, who should have experience with similar medications, will work out what dose is right for you.

How long it is given

Your doctor will decide how long to continue your treatment with Fludarabine ACT.

Unwanted Effects

Like many leukaemia drugs Fludarabine ACT is a very strong drug with many possible side effects, many of which can be very serious. Fludarabine ACT can harm normal blood cells as well as the CLL blood cells, resulting in severe anaemia, abnormal bleeding and bruising and serious infections, especially pneumonia.

Fludarabine ACT can also commonly cause:

- fever and chills,
- infection,
- generally feeling unwell,
- nausea and vomiting,
- tiredness,
- weakness,
- numb or weak limbs,
- build up of fluid in the body tissues,
- visual problems,
- loss of appetite,
- inflammation of the lining of the mouth (stomatitis) and gut,
- skin rashes.

An allergic reaction in the lungs, symptoms of which are difficulties in breathing and coughing can also rarely occur. If you experience any difficulty in breathing or have a cough tell your doctor immediately.

If you notice any unusual bruising, excessive bleeding after injury or if you develop signs of infections (e.g fever, chills, feeling unwell, pain), motor or visual disturbances, tell your doctor immediately.

Further side effects that have occurred in patients with chronic lymphatic leukaemia treated with Fludarabine ACT are:

- peripheral neuropathy (disturbances of the nervous system of your body);
- diarrhoea;
- mucositis;
- stomatitis and uncommonly gastrointestinal bleeding;
- rare cases of haemorrhagic cystitis (inflammation with associated bleeding from the mucosa of the bladder);
- tumour lysis syndrome.

If you notice a pain in your side, blood in your urine or that your stools are tar-coloured or covered with blood tell your doctor immediately.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them. This is not a complete list of all possible side effects.

You should immediately report any side effects that you notice to your specialist or to the nursing staff.

Overdosage

The exact dose of Fludarabine ACT is worked out by your specialist. The dose is determined by your weight and height.

Overdosage is unlikely to occur. In case of an overdose your doctor will stop the therapy and treat the symptoms.

After using Fludarabine ACT

Storage

Fludarabine ACT will usually be stored at the hospital below 25°C and protected from light.

- Fludarabine ACT should be stored where children cannot reach it or see it.
- Fludarabine ACT must not be used after the expiry date stated on the box and on the vial.

Disposal

Any unused medicine must be disposed appropriately by the medical staff.

Product Description

Fludarabine ACT is a white or almost white powder in a glass vial.

It is available as 50 mg/vial.

Each vial is for a single injection only. Fludarabine ACT has to be reconstituted before use.

Ingredients

Fludarabine ACT contains 50 mg Fludarabine phosphate. Other ingredients in the vial are mannitol and sodium hydroxide.

Sponsor

Actavis Pty Ltd
Level 5, 117 Harrington St,
The Rocks NSW 2000

Australian Registration Number:
Fludarabine ACT fludarabine phosphate 50 mg powder for injection vial:
AUST R 147831

This leaflet was updated in November 2013.