FLUDARA ORAL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Fludara Oral?

Fludara Oral contains the active ingredient Fludarabine phosphate. Fludara Oral is used to treat a form of leukaemia known as B-cell chronic lymphocytic leukaemia (B-CLL). This is a cancer of a type of white blood cells called lymphocytes. For more information, see Section 1. Why am I using Fludara Oral? in the full CMI.

2. What should I know before I use Fludara Oral?

Do not use if you have ever had an allergic reaction to Fludarabine phosphate or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information,

see Section 2. What should I know before I use Fludara Oral? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fludara Oral and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Fludara Oral?

- Swallow the tablets whole with a full glass of water. Do not chew or break the tablets.
- The exact number of tablets you should take is calculated by your doctor. The usual dose is between 3 to 10 tablets a day.

More instructions can be found in Section 4. How do I use Fludara Oral? in the full CMI.

5. What should I know while using Fludara Oral?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Fludara Oral • Call your doctor straight away if you notice anything new or unusual

	on your skin, suggestive of skin cancer
Things you should not do	• Do not take Fludara Oral to treat any other complaints unless your doctor tells you to • Do not stop taking your medicine or change the dosage without checking with your doctor
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Fludara Oral affects you
Drinking alcohol	• Tell your doctor if you drink alcohol
Looking after your medicine	• Keep your tablets in the pack until it is time to take them. • Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using Fludara Oral? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are infections, symptoms of anaemia, bruising, loss of appetite, weight loss, numbness or weakness in the arms and legs, cough, nausea, vomiting, diarrhoea, sore mouth or gums, mouth ulcers, skin rash, fever, tiredness, chills, weakness and/or generally feeling unwell, swelling due to excessive fluid retention, severe bruising, more bleeding than usual after injury, infections, symptoms of pneumonia, visual disturbances, sudden signs of allergy, red to brownish urine, rash or any blisters on your skin, vomiting blood or material that looks like coffee grounds, bleeding from your anus or in stools or bloody diarrhoea, seizures, unconsciousness, vision changes, symptoms of heart disease such as shortness of breath, and swelling of the feet or legs due to fluid build-up, abnormal heartbeat, difficulty breathing, severe cough, sharp chest pains, signs of tumour lysis syndrome, signs of Stevens-John syndrome, signs of toxic epidermal necrolysis, neurological disorders, bleeding in the lungs, pain when passing urine. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

FLUDARA ORAL®

Active ingredient(s): *Fludarabine phosphate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fludara Oral. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fludara Oral.**

Where to find information in this leaflet:

1. Why am I using Fludara Oral?
2. What should I know before I use Fludara Oral?
3. What if I am taking other medicines?
4. How do I use Fludara Oral?
5. What should I know while using Fludara Oral?
6. Are there any side effects?
7. Product details

1. Why am I using Fludara Oral?

Fludara Oral contains the active ingredient Fludarabine phosphate. Fludara Oral is an anti-cancer drug approved to treat a form of leukaemia known as B-cell chronic lymphocytic leukaemia (B-CLL). This is a cancer of a type of white blood cells called lymphocytes.

Patients with B-CLL have too many abnormal white blood cells (lymphocytes) and lymph nodes start to grow in various parts of the body. The abnormal white blood cells cannot carry out their normal disease fighting functions, and may push aside healthy blood cells. This can result in infections, a decreased number of red blood cells (anaemia), bruising and/or bleeding.

Fludara Oral is used to stop the growth of new cancer cells. All cells of the body produce new cells like themselves by dividing. To do this, the cells' genetic material (DNA) must be copied and reproduced.

Fludara Oral is taken up by the cancer cells and hinders the production of new DNA.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is not enough information to recommend the use of this medicine for children.

2. What should I know before I use Fludara Oral?

Warnings

Do not use Fludara Oral if:

- You are allergic to Fludarabine phosphate, or any of the ingredients listed at the end of this leaflet

- Always check the ingredients to make sure you can use this medicine
- You are pregnant
- You are breast-feeding
- Your red blood cell count is low because of a type of anaemia (haemolytic anaemia)
- You have severe kidney problems

Check with your doctor if you:

- Have allergies to any other medicines, foods, preservatives or dyes
- Have or have had any of the following medical conditions:
  - low protein in the blood (hypoalbuminaemia). Your doctor will have told you if you have this
  - you feel very unwell, have unusual bruising, more bleeding than usual after injury, or if you seem to be catching a lot of infections
  - poor kidney function
  - enlarged liver or spleen, reduced liver function
  - skin cancer. If you have or have had skin cancer it may worsen or flare up again while you take Fludara Oral or afterwards
- Take any medicines for any other condition
- Are over 75 years of age. Your doctor will administer Fludara Oral to you with caution and monitor your closely
- Are below 18 years of age. It is not recommended to give this medicine to a child under the age of 18 years.

- Are pregnant or plan to become a parent. Men and women who may still be fertile must use a reliable form of contraception during treatment and for at least 6 months after stopping Fludara Oral therapy. It is not known whether Fludara Oral decreases your fertility. Your doctor can discuss with you the risks and benefits involved.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant.

You must not become pregnant during treatment with Fludara Oral because animal studies and very limited experience in humans have shown a possible risk of abnormalities in the unborn baby as well as early pregnancy loss or premature delivery. If pregnancy occurs during your treatment, you must immediately inform your doctor.

It may affect your developing baby if you take it during pregnancy.

You must not breastfeed while you are treated with Fludara Oral.

It is possible that your baby may be affected if you breastfeed.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Fertility in males and females

- Females: you must use an effective method of contraception during and for 6 months after end of treatment, because Fludara Oral may be harmful for the unborn baby.
- Males: you are advised not to father a child during and after end of treatment and to seek advice on conservation of sperm prior to treatment because Fludara Oral may alter male fertility.
- Individual genetic counselling is required for male and female patients before start of Fludara Oral treatment.

3. What if I am taking other medicines?

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

Some medicines may interfere with Fludara Oral and affect how it works. These include:

- Pentostatin (deoxycoformycin) also used to treat B-CLL. Taking these two drugs together can lead to severe lung problems.
- Cytarabine (Ara-C) used to treat chronic lymphatic leukaemia
- Dipyridamole, used to prevent excessive blood clotting, or other similar drugs
- Live viral vaccines. It is recommended that patients do not receive live viral vaccines during and after treatment with Fludara Oral.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fludara Oral.

4. How do I use Fludara Oral?

How much to take / use

- The recommended dose is 40mg per square metre of body surface area, once a day. The exact number of tablets you should take is calculated by your doctor. The usual dose is between 3 to 10 tablets once a day.
- Follow the instructions provided and use Fludara Oral until your doctor tells you to stop.

When to take / use Fludara Oral

- Swallow the tablets whole with a full glass of water. Do not chew or break the tablets
- Fludara Oral can be taken either on an empty stomach or together with food
- Take the tablets the same time every day
- Take the dose worked out by your doctor once a day for 5 consecutive days
- The 5-day-course of treatment will be repeated every 28 days until your doctor has decided that the best effect has been achieved (usually after 6 courses). Your doctor may adjust the dose and number of treatment days
- Attend all of your doctor’s appointments so that your progress can be checked

- You will have blood tests after every treatment course. Your individual dose will be carefully adjusted according to the number of your blood cells and your response to the therapy
- Continue taking your medicine for as long as your doctor tells you
- This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel better

If you forget to use Fludara Oral

Fludara Oral should be used regularly at the same time each day. If you miss your dose at the usual time, or vomit after tablet taking, talk to your doctor as soon as possible.

Do not take a double dose to make up for the dose you missed.

- This may increase the chance of you getting an unwanted side effect
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints

If you use too much Fludara Oral

If you think that you have used too much Fludara Oral, you may need urgent medical attention.

Overdose can cause delayed blindness, coma and even death.

You should immediately:

- phone the Poisons Information Centre **by calling 13 11 26**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Fludara Oral?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Fludara Oral.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Females: you must not become pregnant during treatment with Fludara Oral and must use an effective method of contraception during and for 6 months after end of treatment, because Fludara Oral may be harmful for the unborn baby. If pregnancy occurs during your treatment, you must immediately inform your doctor.

Males: you are advised not to father a child during and after end of treatment and to seek advice on conservation of sperm prior to treatment because Fludara Oral may alter male fertility.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

If you need a blood transfusion, tell your doctor.

Your doctor will ensure that you receive blood that has been treated by irradiation. There have been severe complications and even death, from transfusion of non-irradiated blood.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Check with your doctor before receiving any vaccinations.

Live vaccinations should be avoided during and after treatment with Fludara Oral.

Call your doctor straight away if you:

- Notice anything new or unusual on your skin, suggestive of skin cancer
- If you have or have had skin cancer it may worsen or flare up again while you take Fludara Oral or afterwards. You may also develop skin cancer during

or after Fludara Oral therapy as it reduces your body's defence mechanisms.

Remind any doctor, dentist or pharmacist you visit that you are using Fludara Oral.

Things you should not do

- Fludara Oral must not be administered if you are pregnant unless clearly indicated by your doctor
- Do not breastfeed while you are being treated with Fludara Oral
- Do not take Fludara Oral to treat any other complaints unless your doctor tells you to
- Do not give your medicine to anyone else, even if they have the same condition as you
- Do not stop taking your medicine or change the dosage without checking with your doctor
- If you stop taking it suddenly, your condition may worsen

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Fludara Oral affects you.

Fludara Oral may cause fatigue, weakness, visual disturbances, confusion, agitation and whist rare seizures in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them
- If you take the tablets out of the pack they may not keep well
- Keep your tablets in a cool dry place where the temperature stays below 25°C
- Heat and dampness can destroy some medicines

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

Keep it where young children cannot reach it.

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

When to discard your medicine

If your doctor tells you to stop taking this medicine, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

This medicine helps most people with B-cell chronic lymphocytic leukaemia (B-CLL), but it may have unwanted side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Infections with symptoms of: • Fever • Severe chills • Sore throat • Mouth ulcers	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
Symptoms of anaemia such as: • Tiredness • Headaches • Being short of breath when exercising • Dizziness • Looking pale **Other:** • Some bruising • Loss of appetite leading to weight loss • Numbness or weakness in the arms and legs • Cough • Nausea, vomiting, diarrhoea • Sore mouth or gums • Mouth ulcers • Skin rash • Fever • Tiredness • Chills • Weakness and/or generally feeling unwell	

Less serious side effects	What to do
• Swelling due to excessive fluid retention	

Serious side effects

Serious side effects	What to do
• Severe bruising • More bleeding than usual after injury • You seem to be catching a lot of infections • Anything new or unusual on your skin such as mole, freckle or sore; a spot, mole or freckle that has changed in colour, shape or size • Symptoms of pneumonia such as fever, chills, shortness of breath, cough and phlegm that may be blood stained • Visual disturbances • Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips,	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
tongue or other parts of the body, shortness of breath, wheezing or trouble breathing • Red to brownish urine, rash or any blisters on your skin • Vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea • Seizures, unconsciousness • Sudden dimming or loss of vision • Symptoms of heart disease such as shortness of breath, and swelling of the feet or legs due to fluid build-up • Abnormal heartbeat (irregular, fast or slow) • Difficulty breathing, shortness of breath, severe cough, sharp chest pains	

Serious side effects	What to do
• Signs of tumour lysis syndrome such as pain in one side of the body under the rib cage, little or no urine, drowsiness, nausea, vomiting, breathlessness, irregular heart beat, loss of memory, loss of consciousness • Signs of Stevens-John syndrome, such as skin and/or mucous membrane reaction with redness, inflammation, blistering and erosion • Signs of toxic epidermal necrolysis which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell • Neurological disorders manifested by headache, feeling sick (nausea) and vomiting,	

Serious side effects	What to do
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) or increased intracranial pressure) • Bleeding in the lungs • Inflammation of the bladder, which can cause pain when passing urine, and can lead to blood in the urine (haemorrhagic cystitis)	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Keep all doctor's appointments so your progress can be checked.

Some side effects (for example, blood disorders) can only be found when your doctor does tests on a regular basis.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Fludara Oral contains

Active ingredient **(main ingredient)**	Fludarabine phosphate

Other ingredients (inactive ingredients)	Microcrystalline cellulose Sugars as lactose Colloidal anhydrous silica Croscarmellose sodium Magnesium stearate Hypromellose Purified talc Titanium dioxide Iron oxide red CI 77491 Iron oxide yellow CI 77492
Potential allergens	Not Applicable

Do not take this medicine if you are allergic to any of these ingredients.

What Fludara Oral looks like

Fludara Oral film-coated tablets are salmon coloured oval shaped with “LN” indented in a regular hexagon on one side. The tablets are packaged in Al/Al blister packs of 20 tablets (each blister foil contains 5 tablets) (Aust R 81998).

Who distributes Fludara Oral

Distributed by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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