FLUDARA ORAL® (FLU-DA-RA)

Fludarabine phosphate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FLUDARA ORAL. 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 taking FLUDARA ORAL against the benefits they expect it will have for you.

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

What FLUDARA ORAL is used for

This medicine 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 is a medication that stops 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 is taken up by the cancer cells and hinders the production of new DNA.

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

Your doctor may have prescribed it for another reason.

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

Before you take FLUDARA ORAL

When you must not be given it

Do not have any FLUDARA if you have an allergy to:
- any medicine containing fludarabine
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction 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

Do not have FLUDARA if you
- are pregnant
- are breast-feeding
- your red blood cell count is low, because of a type of anaemia (haemolytic anaemia)
- have severe kidney problems

Do not take this medicine if you are pregnant.
It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.
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.

Before you take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you 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 fell 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 or afterwards.

Tell your doctor if you are over 75 years of age.
Your doctor will administer FLUDARA to you with caution and monitor you closely.

Tell your doctor if the person is below 18 years of age.
It is not recommended to give this medicine to a child under the age of 18 years.

Tell your doctor if you 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 therapy. It is not known whether FLUDARA decreases your fertility. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you take FLUDARA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.
Some medicines and FLUDARA may interfere with each other. These include:

- pentostatin (deoxycoformycin) also used to treat B-CLL. Taking these two drugs together can lead 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.

These medicines may be affected by FLUDARA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor may have more information on medicines to be careful with or avoid while taking this medicine.

How to take FLUDARA ORAL

FLUDARA should be administered under the supervision of a qualified physician experienced in the use of cancer therapy. The dose you should take depends on your body surface area. This is measured in square metres (m²), and is worked out by the doctor from your height and weight.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions you have been given, ask your doctor or pharmacist for help.

How to take it

Swallow the tablets whole with a full glass of water. Do not chew or break the tablets.

When to take it

Take the tablets the same time every day.
FLUDARA can be taken either on an empty stomach or together with food.

How much to take

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.

How long to take it

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 take it

Talk to your doctor as soon as possible if you think you may have missed a dose or vomit after tablet taking. Do not take a double dose to make up for the forgotten tablets.
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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) or New Zealand National Poisons Information Centre (telephone 0800 764 766, or 0800 POISON) 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 FLUDARA. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Overdose can cause delayed blindness, coma and even death.

While you are using FLUDARA ORAL

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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.

If you notice anything new or unusual on your skin, suggestive of skin cancer, tell your doctor.
If you have or have had skin cancer it may worsen or flare up again while you take FLUDARA or afterwards. You may also develop skin cancer during or after FLUDARA therapy as it reduces your body's defence mechanisms.

If you are a fertile male or female of childbearing potential, ensure that you use a reliable form of birth control during treatment and for at least 6 months after treatment. If you do become pregnant while taking this medicine, tell your doctor immediately.
The effects of this medicine on reproduction are unknown.

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.

Things you must not do

Do not take FLUDARA 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.

Things to be careful of

Be careful driving or operating machinery until you know how FLUDARA affects you.
This medicine 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FLUDARA.

This medicine helps most people with B-cell chronic lymphocytic leukaemia (B-CLL), but it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:
- infections with symptoms of fever, severe chills, sore throat or mouth ulcers
- symptoms of anaemia such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- 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
- swelling due to excessive fluid retention.

The above list includes the more common side effects of your medicine. They are often mild or moderate problems that are short-lived and diminish during the course of treatment. **However, if you believe the side effect is of a more severe nature, tell your doctor as soon as possible.**

Tell your doctor as soon as possible of you notice any of the following:
- 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.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, 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)
- difficultly breathing, shortness of breath, severe cough, sharp chest pains
- 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, 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)*)
- 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)*

The above list includes very serious side effects. You may need medical attention or hospitalisation. These side effects are usually uncommon or rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.
Other side effects not listed above may also occur in some people.

Keep all doctors appointments do 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.

After using FLUDARA ORAL

Storage

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.

Do not store FLUDARA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres about the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

FLIDARA ORAL film-coated tablets are salmon coloured oval shaped with “LN” indented in a regular hexagon on one side. The tablets are packaged in blisters of 5 tablets and three or four blisters are packed in child resistant containers.

Ingredients

Each FLUDARA ORAL tablet contains 10mg of fludarabine phosphate.

It also contains:

- microcrystalline cellulose
- lactose
- Colloidal silicon dioxide
- croscarmellose sodium
- magnesium stearate
- hypromellose
- purified talc
- titanium dioxide
- iron oxide red
- iron oxide yellow

Sponsor

In New Zealand this product is distributed by:

sanofi-aventis new zealand limited

56 Cawley Street, Ellerslie,
Auckland
New Zealand
Toll Free Number (medical information): 0800 283 684 (option 2)

Date of preparation: 11 May 2021

fludara-oral-ccdsv26-cmiv4-11may21