Teva Pharmaceuticals (Pty) Ltd.

Fludarabine 50 Teva

(Concentrate for Solution for injection or Infusion)

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

FLUDARABINE 50 TEVA, Concentrate for solution for injection or infusion

Fludarabine phosphate

Contains sugar: 50,0 mg mannitol per 2 ml vial

Read all of this leaflet carefully before you are given FLUDARABINE 50 TEVA:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor pharmacist, nurse or other healthcare provider.
- FLUDARABINE 50 TEVA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT FLUDARABINE 50 TEVA IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLUDARABINE 50 TEVA

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1. WHAT FLUDARABINE 50 TEVA IS AND WHAT IT IS USED FOR:

FLUDARABINE 50 TEVA belongs to the group of medicines called antineoplastics, which interferes with the growth of cancer cells to eventually destroy the cancer cells. FLUDARABINE 50 TEVA is used to treat chronic lymphatic leukaemia (CLL), a type of cancer.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLUDARABINE 50 TEVA:

FLUDARABINE 50 TEVA should not be administered to you:

- If you are hypersensitive (allergic) to fludarabine, the active ingredient or any of the other ingredients of FLUDARABINE 50 TEVA (listed in **section 6**).
- If you are pregnant or breastfeeding your baby (see section **Pregnancy and breastfeeding**).
- If your kidney function is severely impaired or you have a kidney disease
- If you have anaemia
- If you have chickenpox or shingles.

Warnings and precautions:

Tell your doctor or healthcare provider before being given the injection:

Take special care with FLUDARABINE 50 TEVA:

- It is very important that your doctor checks your progress at regular visits to make sure that FLUDARABINE 50 TEVA is working properly and to check for unwanted effects.
- Some of the side effects of FLUDARABINE 50 TEVA do not have any symptoms and must be found with a blood test.
- FLUDARABINE 50 TEVA should only be used in specialized cancer departments and under the supervision of a doctor that specializes in cancer treatment.
- If you should have a blood transfusion, it is advised that you should receive irradiated blood only.
- If you have a history of opportunistic infection.
- FLUDARABINE 50 TEVA can temporarily lower the number of white blood cells in your blood, increasing the chance of getting an infection. It can also lower the number of platelets, which are needed for proper blood clotting. If this occurs, there are certain precautions you can take, especially when your blood count is low, to reduce the risk of infection or bleeding:
- If you can avoid people with infections.
- Be careful when using a regular toothbrush, dental floss or toothpick.

- Do not touch your eyes or the inside or your nose unless you have just washed your hands and have not touched anything else in the meantime.
- Be careful not to cut yourself when you are using a sharp object such as a razor or fingernail or toenail cutters.
- Avoid contact sports or other situation where bruising or injury could occur.
- Your doctor will monitor you for side effects related to the brain, spinal cord and nerves such as headache, nausea and vomiting, seizures, visual disturbances such as vision loss, optic neuritis (pain with eye movement, and impaired color vision), increased sleepiness and agitation.

Children and adolescents:

The safety and effectiveness of FLUDARABINE 50 TEVA in children has not been established.

Other medicines and FLUDARABINE 50 TEVA:

Always tell your healthcare provider if you are taking any other medicine (This includes all complementary or traditional medicines).

Please consult your doctor, pharmacist or other healthcare provider for advice if you are using any of the following medicines:

- Sulfinpyrazone, allopurinol, probenecid and/or colchicine (medicine for gout)
- Bone marrow depressants
- Dipyridamole (medicine that prevents blood clots)
- Pentostatin (anticancer drug to treat leukaemia)
- Corticosteroids
- Aminoglycosides (antibiotic such as gentamycin or neomycin)

Tell your doctor that you are using FLUDARABINE 50 TEVA if you are going to be vaccinated.

FLUDARABINE 50 TEVA may lower your body's resistance and there is a chance you might get the infection the immunisation is meant to prevent. Whether to vaccinate or not, should be clarified with the treating doctor.

Not all the medicines that would interact with FLUDARABINE 50 TEVA are listed above, please tell your doctor or healthcare provider about any other medicine that you are using, prior to using FLUDARABINE 50 TEVA.

FLUDARABINE 50 TEVA with food and drink:

Discuss with your healthcare provider the use of FLUDARABINE 50 TEVA with food, alcohol or tobacco. Avoid eating foods that may make nausea worse, such as fatty, fried or spicy foods.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnant women should not handle FLUDARABINE 50 TEVA.

FLUDARABINE 50 TEVA should not be used if you are pregnant or breastfeeding your baby.

Women of childbearing age should use effective method of birth control during treatment with FLUDARABINE 50 TEVA and for 6 months after stopping treatment. Tell your doctor right away if you think you have become pregnant while receiving FLUDARABINE 50 TEVA.

Males with female partners who are able to become pregnant should use effective birth control during treatment with and for 3 months after your last dose of FLUDARABINE 50 TEVA.

Driving and using machines:

FLUDARABINE 50 TEVA may cause some people to become nauseous and to have headaches and blurred vision.

It is not always possible to predict to what extent FLUDARABINE 50 TEVA may interfere with the daily activities of a patient. *Do not drive or operate any machinery before you know how FLUDARABINE 50 TEVA affects you.*

3. HOW TO USE FLUDARABINE 50 TEVA:

Do not share medicines prescribed for you with any other person.

FLUDARABINE 50 TEVA should only be used in specialised cancer departments and under the supervision of a doctor that specialises in cancer treatment. FLUDARABINE 50 TEVA is for intravenous use only. The dose of FLUDARABINE 50 TEVA will be different for different patients. Your doctor will decide on the suitable dose and the duration of your treatment based on your specific needs and medical condition. If FLUDARABINE 50 TEVA solution comes into contact with your skin, wash immediately and thoroughly with soap and water.

If you receive more FLUDARABINE 50 TEVA than you should:

Since a healthcare provider will administer FLUDARABINE 50 TEVA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use FLUDARABINE 50 TEVA:

Since a healthcare provider will administer FLUDARABINE 50 TEVA, it is unlikely that the dose will be missed.

If you stop using FLUDARABINE 50 TEVA:

You and your doctor may decide to stop your treatment with FLUDARABINE 50 TEVA if the side effects are becoming too severe.

4. POSSIBLE SIDE EFFECTS:

FLUDARABINE 50 TEVA can have side effects.

Not all side effects reported for FLUDARABINE 50 TEVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving FLUDARABINE 50 TEVA, please consult your healthcare provider for advice.

FLUDARABINE 50 TEVA also affects the growth of normal cells, which may result in side effects. Some of these side effects may be serious and must be reported to your doctor.

Some side effects may occur after treatment with FLUDARABINE 50 TEVA has been stopped.

Be sure that you discussed with your doctor the possible side effects of FLUDARABINE 50 TEVA as well as the good it can do.

If any of the following happens, stop taking/using FLUDARABINE 50 TEVA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- if you have difficulty breathing, have a cough, or have chest pain with or without fever. These may be signs of an infection of the lungs,
- if you notice any unusual bruising, more bleeding than usual after injury or if you seem to be catching a lot of infections. These may be caused by a reduced number of blood cells. This may also lead to an increased risk of (serious) infections, caused by organisms, that usually do not cause disease in healthy persons (opportunistic infections) including a late reactivation of viruses, for example herpes zoster,
- if you notice any pain in your side, blood in your urine, or reduced amount of urine. These may be signs of tumour lysis syndrome (see **section 2**),
- if you have rapid or irregular heartbeat or chest pain. These may be signs of heart problems.

These are all very serious side effects. If you have them, you may have had a serious reaction to FLUDARABINE 50 TEVA. You may need urgent medical attention or hospitalisation.

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

- angina
- if you notice any skin and/or mucous coat reaction with redness, inflammation, blistering and tissue break down. These may be signs of a severe allergic reaction (Stevens-Johnson syndrome).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- black tarry stools
- sores, ulcers or white spots on lips or in mouth
- bleeding in the stomach or intestines
- nausea and vomiting
- runny stomach
- inflammation of the inside of the mouth (stomatitis)
- skin rash
- feeling depressed
- numbness or tingling in fingers toes or face
- muscle pain or stiffness
- cough
- swelling due to excessive fluid retention (oedema)
- loss of appetite and weight loss
- urinary infection
- tiredness
- fever, chills, sweating more than usual
- weakness

Less frequent side effects:

- bleeding gums, coughing blood, nosebleeds
- constipation, difficulty swallowing
- inflammation of the mucous coat of the digestive system from the mouth to the anus (mucositis), gallstones
- inflammation of the oesophagus
- hair loss, oily skin
- agitation, coma, confusion, blindness, sleep disorder and damage to the brain or peripheral nervous system caused natural exposure or man-made toxic substances
- joint pain, bone loss
- sinus infection, inflamed airways causing coughing and mucus production, low levels of oxygen in the blood
- blurred vision, inflammation or damage of the nerve of the eyes
- bleeding in the brain, blood clot and/or inflammation in a deep vein, low levels of oxygen in body tissues
- changes in the levels of potassium (too high levels of potassium), phosphates (too high levels of phosphate), calcium (too low levels of calcium)
- hearing loss
- too high levels of uric acid causing symptoms such as gout, in your blood
- liver failure
- kidney failure
- inflammation of the bladder, which can cause pain when passing urine, and can lead to blood in the urine (haemorrhagic cystitis)
- abnormal pancreatic enzymes.

Side effects with unknown frequency:

- laboratory finding of too few red blood cells, white blood cells and platelets

- 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) (Multifocal leukoencephalopathy)
- lung toxicity, scarring throughout the lungs (pulmonary fibrosis), inflammation of the lungs (pneumonitis)
- changes in your liver or pancreatic enzyme levels (causing symptoms such as jaundice, fatigue, nausea, vomiting, pain of your stomach area, mental changes or itching).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FLUDARABINE 50 TEVA.

5. HOW TO STORE FLUDARABINE 50 TEVA:

Store all medicines out of reach of children.

- Store between 2 to 8 °C. Do not freeze.
- Inspect visually prior to use. Only clear solutions without particles should be used. The medicine is for single use only. Any unused solution should be discarded.
- When diluted to final concentration range of 0,3 to 6,0 mg/ml in 5 % glucose for injection or in 0,9 % sodium chloride for injection the solution has to be used within 72 hours, when stored at 5 °C ± 3 °C or at ambient room temperature and light conditions.

- From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2 °C to 8 °C or 8 hours at room temperature.
- Do not use FLUDARABINE 50 TEVA after the expiry date printed on the carton or vial.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What FLUDARABINE 50 TEVA contains:

Each FLUDARABINE 50 TEVA 2 ml vial contains fludarabine phosphate 25 mg/1 ml as the active ingredient. FLUDARABINE 50 TEVA solution contains the following inactive ingredients: mannitol, and water for injection.

What FLUDARABINE 50 TEVA looks like and contents of the pack:

FLUDARABINE 50 TEVA is a clear, colourless or lightly brownish-yellow solution, essentially free from particles.

FLUDARABINE 50 TEVA is packed in a tubular type I glass, colourless injection vial (2R or 2 ml) with grey bromobutyl rubber stopper; silver aluminium flip-off seal and blue polypropylene snap-cap. One vial is packed in the outer carton.

Holder of Certificate of Registration:

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