Scheduling Status:
S3

ALORIBEX 100 mg tablets
ALORIBEX 300 mg tablets

Allopurinol
Sugar free.

Read all of this leaflet carefully before you start taking ALORIBEX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ALORIBEX 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 ALORIBEX is and what it is used for:

ALORIBEX contain a medicine called allopurinol. It works by slowing down the speed of certain chemical reactions in your body to lower the level of uric acid in your blood and urine.

ALORIBEX is used to reduce or prevent the formation of urate/uric acid deposition in conditions where your body produces too much of a substance called uric acid. These may include gout or some types of kidney stones, or certain other types of kidney problems, or when you are having treatment for cancer or some other conditions. In gout the uric acid builds up in your joints and tendons as crystals. These crystals cause an inflammatory reaction. The inflammation causes the skin around certain joints to become swollen, tender and sore when only slightly touched. You can also find you get severe pain when the joint is moved.

2. What you need to know before you take ALORIBEX:

Do not take ALORIBEX:

- If you are hypersensitive (allergic) to allopurinol or any of the other ingredients of ALORIBEX (see What ALORIBEX contains). If you have a severe kidney or liver problem.
- If you are currently having an acute attack of gout.
- If you developed serious adverse effects from ALORIBEX.
- Children, except those diagnosed with a certain type of cancer.
- If you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

Warnings and precautions:

Take special care with ALORIBEX:

- ALORIBEX treatment should be stopped immediately if any skin rash or allergic reaction occurs. Contact your doctor for advice if you develop a skin rash once starting treatment with ALORIBEX.
- If you have a liver or kidney disorder.
- If you suffer from high blood pressure or a heart disorder and you are taking medicines to treat these conditions, such as diuretics or ACE inhibitors.
- ALORIBEX should not be used to treat an acute attack of gout. ALORIBEX may cause an acute attack when starting treatment initially. Your doctor may prescribe additional medicines during the first month of ALORIBEX treatment.
- If you have cancer or Lesch-Nyhan syndrome the amount of uric acid may increase in your urine. To prevent this, you need to assure to drink sufficiently to dilute your urine.
- If you have kidney stones, the kidney stones will become smaller and may enter your urinary tract.
- If you have thyroid problems.

Other medicines and ALORIBEX

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

Tell your doctor or pharmacist if you are currently using:

- Vidarabine (used to treat herpes or chickenpox).
- Medicines used in the treatment of certain types of cancers, such as mercaptopurine, azathioprine and other anti-neoplastic medicines.
- Medicines that can increase uric acid concentration, such as aspirin or other salicylates (used for pain and inflammation).
- Chlorpropamide (used to treat diabetes).
- Medicines used to thin your blood (anticoagulants), such as warfarin.

- Phenytoin (used to treat epilepsy).
- Theophylline (used for breathing problems).
- Ampicillin or amoxicillin (antibiotics used to treat bacterial infections).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Didanosine (used to treat HIV/AIDS).
- Medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics).
- Antacids (used to treat heartburn or indigestion).
- Aluminium hydroxide and ALORIBEX should not be taken together. There should be an interval of at least 3 hours between taking both medicines.

ALORIBEX with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding and fertility

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 ALORIBEX.

Do not take ALORIBEX during pregnancy or breastfeeding (see section 2).

Driving and using machines

ALORIBEX can cause side effects, such as drowsiness, dizziness and coordination problems and can interfere with your ability to drive a vehicle or operate machinery. If this happens to you, do not engage in activities which require you to be alert; for example, driving a car and using machinery.

3. How to take ALORIBEX:

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

Always take ALORIBEX exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults:

Gout: The usual dose is 50 mg twice daily, and then to increase this dose as required up to 200 mg to 400 mg daily in divided doses. Your doctor will decide on the correct dose, depending on your body's response.

Hyperuricaemia associated with leukaemia: The initial dose is 200 mg three times daily, starting, if possible, 2 or 3 days before radiotherapy. The usual maintenance dose is 300 mg to 400 mg daily.

Children:

Your doctor will determine the dose based upon the weight of your child.

You should take adequate amounts of fluid (at least 2 litres) during the day while on treatment with ALORIBEX.

ALORIBEX can be taken with or without food.

Your doctor will tell you how long your treatment with ALORIBEX will last. If you have the impression that the effect of ALORIBEX is too strong or too weak, tell your doctor or pharmacist.

If you take more ALORIBEX than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining ALORIBEX with you so the doctor will know what you have taken.

If you forget to take ALORIBEX

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take ALORIBEX at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

ALORIBEX can have side effects.

Not all side effects reported for ALORIBEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ALORIBEX, please consult your health care provider for advice.

If any of the following happens, stop taking ALORIBEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ALORIBEX. 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:

- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Unexplained bleeding or bruising more easily than normal.
- Feeling unable to move muscles (paralysis) or loss of consciousness.
- Fits (seizures).
- Chest pain (angina).
- Changes in the way your heart beats (beating faster or slower than normal).
- Vomiting blood.
- Yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Cancer that begins in white blood cells called T cells (angioimmunoblastic T-cell lymphoma).
- Aseptic meningitis (inflammation of the membranes that surround your brain and spinal cord, causing symptoms such as neck stiffness, headache, nausea, fever).
- Blood in your urine.

Side effects occurring less frequently:

- Boils (red, raised bumps on your skin caused by infection around the hair follicles).
- Anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration).
- Vasculitis (inflammation of your blood vessels, which can cause fever, headache, fatigue, weight loss, general aches and pains, night sweats, nerve problems such as numbness or weakness).
- High blood sugar levels (diabetes).
- High levels of cholesterol in your blood (hyperlipidaemia).
- Drowsiness or sleepiness.
- Being in a sad mood for long periods of time (depression).
- Lack of voluntary coordination of muscle movements (ataxia).
- Tingling or numbness in your hands or feet.
- Headache.
- A change in taste.
- Cataract formation or change in your eyesight.

- Vertigo (sensation of spinning or swaying).
- High blood pressure.
- Nausea (feeling sick), vomiting (being sick), stomach pain, diarrhoea, inflamed and sore mouth, a change in your bowel habits, presence of fat in your stool.
- Abnormal liver function results when blood tests are done.
- Hair loss or discoloured hair.
- Joint pain.
- Increased urea and creatinine levels in your blood when blood tests are done.
- Male infertility, impotence (inability to have or maintain an erection), breast enlargement in men.
- Feeling unwell or general feeling of weakness.
- Fever or chills.
- Increased thyroid levels when blood tests are done.

Side effects occurring with an unknown frequency:

- Spontaneous orgasm during sleep.

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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ALORIBEX.

5. How to store ALORIBEX:

- Store at or below 25 °C.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton/blister.
- 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 ALORIBEX contains

ALORIBEX 100: Each tablet contains 100 mg allopurinol.

ALORIBEX 300: Each tablet contains 300 mg allopurinol.

The other ingredients are cellulose powder, crospovidone, macrogol 4000, magnesium stearate, microcrystalline cellulose, povidone and purified talc.

What ALORIBEX looks like and contents of the pack

ALORIBEX 100: White, round, biconvex tablets with a score notch on one side.

ALORIBEX 300: White, round, biconvex tablets with a score notch on one side.

ALORIBEX 100: Clear PP / Aluminium blisters blister strips. 10 (10) blister strips to be packed into a carton i.e. 100 tablets per carton OR Clear PVC / Aluminium blisters blister strips. 10 (10) blister strips to be packed into a carton i.e. 100 tablets per carton.

ALORIBEX 300: Clear PP / Aluminium blisters blister strips. 10 (10) blister strips to be packed into a carton i.e. 100 tablets per carton OR Clear PVC / Aluminium blisters blister strips. 10 (10) blister strips to be packed into a carton i.e. 100 tablets per carton.

Holder of Certificate of Registration:

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