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Patient Information Leaflet

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:
DIZOVIN 100 CAPSULES
DIZOVIN 300 TABLETS

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING DIZOVIN
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **DIZOVIN** 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 DIZOVIN CONTAINS:
DIZOVIN 100 CAPSULES
Each capsule contains zidovudine 100 mg.
Excipients: microcrystalline cellulose, corn starch, sodium starch glycolate, magnesium stearate, hard gelatin capsules size 3: titanium dioxide, gelatin, sodium lauryl sulfate.

DIZOVIN 300 TABLETS
Each tablet contains zidovudine 300 mg.
Excipients: microcrystalline cellulose, sodium starch glycolate, povidone K 29/32, magnesium stearate, colourant: Hypromellose, Titanium dioxide, Macrogol 400.

WHAT DIZOVIN IS USED FOR:
DIZOVIN is used to treat HIV (human immunodeficiency virus) infection.
DIZOVIN is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs).* **DIZOVIN** does not get rid of HIV infection; it reduces the amount of virus in your body, and keeps it at a low level.
DIZOVIN is used, in combination with other antiretroviral medicines to treat HIV in adults and children greater than 12 years of age. If you are pregnant, your doctor may want you to take **DIZOVIN**, to help prevent you passing HIV on to your unborn baby. After the birth, your baby may be given an oral medicine to help prevent it from getting infected with HIV.

BEFORE YOU TAKE DIZOVIN:
Do not take DIZOVIN:
It is important that you tell your doctor or healthcare professional if you suffer from any of the conditions mentioned below, if you are taking DIZOVIN or have been prescribed DIZOVIN.
- If you are hypersensitive (allergic) to zidovudine or to any of the ingredients contained in **DIZOVIN.**
- If you have had severe allergic reactions such as anaphylaxis or Stevens-Johnson syndrome (rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals) to any of the ingredients contained in **DIZOVIN**.
- If you have a very low white blood cell count *(neutropenia)* or a very low red blood cell count *(anaemia)*.
- If you are currently taking stavudine for the treatment of HIV infection.
- Children less than 3 months should not be given **DIZOVIN.**

Take special care with DIZOVIN:
Caution should be observed with the use of **DIZOVIN** in the following patients:
- If you have ever had liver disease (including hepatitis B or C), as treatment with **DIZOVIN** in patients with liver disease could cause severe side effects affecting the liver including death. Your doctor will monitor your liver function by performing blood tests on a regular basis.
- If you have an ongoing hepatitis B infection, do not stop **DIZOVIN** without your doctor's advice, as your hepatitis may come back. The hepatitis may be more severe if you also have a serious liver disease.
- If you are seriously overweight (especially if you're a woman).
- Inform your doctor if you experience symptoms such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale while taking **DIZOVIN**. You may have a condition known as anaemia, a condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal or a condition in which there is a decreased number of red blood cells. Your doctor will monitor your haemoglobin and red blood cell count by performing regular blood tests and adjust the dose of **DIZOVIN** if required. Severe cases of anaemia may require blood transfusions or discontinuation of **DIZOVIN.**
- Inform your doctor if you experience symptoms of frequent infections such as fever, severe chills, sore throat or mouth ulcers while taking **DIZOVIN.** You may have neutropenia which is a lack of white blood cells. Your doctor will monitor your white blood cell count by performing regular blood tests and adjust the dose of **DIZOVIN** if required.
- **DIZOVIN** may cause muscle disease (myopathy) and symptoms include aching muscles, muscle tenderness or weakness which is not caused by exercise.
- Long term use of **DIZOVIN** may lead to an increase of acid in your body, and includes signs such as nausea, vomiting, stomach pain and cramps, weight loss, shortness of breath or fast breathing and fatigue. You may have a condition known as "lactic acidosis". Stop taking **DIZOVIN** and consult your doctor immediately.
- Take your child, if exposed during pregnancy or after birth to **DIZOVIN,** to your doctor immediately if your child appears pale, weak, sleepy all the time, is breathing faster, the heart is beating faster, the child does not appear to be putting on weight, is vomiting, has fever, sore throat, mouth ulcers, appears stiff, has convulsions (fits) or behaving abnormally. Your doctor will perform additional medical and laboratory tests on your child.
- **DIZOVIN** may cause inflammation of the pancreas. Inform your doctor if you experience severe upper stomach pain with nausea (feeling sick) and vomiting.
- Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys. The dose of **DIZOVIN** may have to be adjusted.
- Inform your doctor, if you notice changes in body shape and weight including increase of weight around the waist, on the back of the neck between the shoulders and enlargement of the breasts or if you are losing weight in other areas of your body. **DIZOVIN** may also increase levels of sugar and fats (triglycerides and cholesterol) in the blood.
- You may experience an increase in other infections during initial treatment with **DIZOVIN** combined with other HIV medicine if your immune system is compromised. People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections. When starting treatment you might find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections. If you notice any symptoms of infection, please inform your doctor immediately.
- Long term treatment with **DIZOVIN** in combination with other medicines to treat HIV may cause osteonecrosis which is bone death caused by poor blood supply to the area. It is most common in the hip and shoulder, but can affect other large joints such as knee, elbow, wrist and ankle.
- **DIZOVIN** is not a cure for HIV infection. **DIZOVIN** helps to control your condition and you need to keep taking it every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.
- Keep in touch with your doctor, and do not stop taking **DIZOVIN** without your doctor's advice.
- HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). **DIZOVIN** will not stop you passing HIV infection on to other people.

To protect other people from becoming infected with HIV:
  - Use a condom when you have oral or penetrative sex.
  - Do not risk blood transfer – for example, do not share needles.
- Babies of mothers given **DIZOVIN** to prevent transmission of HIV from mother to child during childbirth, may become anaemic. Inform your doctor if your child appears pale, weak, sleepy all the time, is breathing faster, the heart is beating faster and the child does not appear to be putting on weight.

Talk to your doctor if any of these applies to you. You may need extra check-ups, including blood tests, while you are taking your medicine.

DIZOVIN 100 CAPSULES
DIZOVIN 300 TABLETS
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Taking DIZOVIN with food and drink:
DIZOVIN may be taken with or without food.
Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **DIZOVIN.**

DIZOVIN can be given to pregnant women, after 14 weeks of pregnancy until the beginning of labour.
Pregnant women considering the use of **DIZOVIN** during pregnancy for prevention of HIV transmission to their babies should be advised that the transmission may still occur despite therapy. It is therefore recommended that mothers taking **DIZOVIN** do not breastfeed their babies. The safety of **DIZOVIN** for the mother and foetus during the first three months of pregnancy has not been established.

DIZOVIN is excreted in human milk.
Mothers should therefore discontinue breastfeeding if they are taking **DIZOVIN**, because of the potential for side-effects from **DIZOVIN** in their breastfed babies. Women infected with HIV should not breastfeed their babies in order to avoid transmission of HIV to their babies.

Driving and the use of machinery:
Dizziness, impaired concentration, and drowsiness have been reported during treatment with **DIZOVIN.** If you experience these symptoms, you should avoid potentially hazardous tasks such as driving or operating machinery.

Taking other medicines with DIZOVIN:

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

DIZOVIN may change the effect of other medicines and other medicines may change the effect of **DIZOVIN.** When you are taking **DIZOVIN,** it is especially important to tell your doctor or healthcare professional if you are taking any of the following:
- stavudine, used to treat HIV infection
- rifampicin, which is an antibiotic.

Some medicines can make it more likely that you will have side effects, or make side effects worse. These include:
- valproate, used to treat epilepsy
- aciclovir, ganciclovir or interferon, used to treat virus infections
- pyrimethamine, used to treat malaria and other parasitic infections
- dapsone, used to prevent pneumonia and treat skin infections
- fluconazole or flucytosine, used to treat fungal infections such as candida
- pentamidine or atovaquone, used to treat parasitic infections such as PCP (pneumocystis pneumonia)
- amphotericin or co-trimoxazole, used to treat fungal and bacterial infections
- probenecid, used to treat gout
- methadone, used to relieve severe pain and to prevent withdrawal symptoms in people who are addicted to opiate drugs such as heroin
- vincristine, vinblastine or doxorubicin, used to treat some types of cancer.

Tell your doctor if you're taking any of these. Some medicines interact with **DIZOVIN.**
These include:
- clarithromycin, which is an antibiotic
- phenytoin, used for treating epilepsy.

Tell your doctor if you are taking clarithromycin or phenytoin. Your doctor may need to monitor you while you are taking **DIZOVIN.**

HOW TO TAKE DIZOVIN:

Do not share medicines prescribed for you with any other person.
Always take DIZOVIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of DIZOVIN is too strong or too weak talk to your doctor or pharmacist.

Your doctor will determine your dose based on your body weight, kidney and liver function, and any side effects that you may have had with other medicines. Take **DIZOVIN** exactly as instructed. **DIZOVIN** tablets and capsules are usually taken twice a day (every 12 hours).You may take **DIZOVIN** with or without food.

Pregnancy, childbirth and newborn babies:
You should not normally take **DIZOVIN** during the first 14 weeks of your pregnancy. After week 14, the usual dose is 500 mg each day in divided doses until you start to go into labour. During the labour and birth, your doctor may give you injections of a zidovudine medicine until your baby's umbilical cord has been clamped. Your new-born baby may also be given an oral solution containing zidovudine to help prevent it from getting infected with HIV.

People with kidney or liver problems:
If you have severe kidney or liver problems, you may be given a lower dose of **DIZOVIN**, depending on how well your kidneys or liver are working. Follow your doctor's advice.

If you take more DIZOVIN than you should:
If you have accidently taken too much **DIZOVIN,** get medical help immediately by calling your nearest doctor or healthcare professional.

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

If you forget to take DIZOVIN:
Do not miss a dose of **DIZOVIN**, as this could make the virus harder to treat. If you have missed a dose of **DIZOVIN**, take it as soon as you remember. However if it is almost time for your next dose, skip the missed dose and go back to your regular scheduling. Never double your dose.

POSSIBLE SIDE EFFECTS:
DIZOVIN can have side effects.
Not all the side effects reported for **DIZOVIN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **DIZOVIN**, please consult your doctor, pharmacist or healthcare professional for advice.

*If any of the following happen, stop taking **DIZOVIN** and tell your doctor immediately or go to the casualty department at your nearest hospital:*
- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, rash or itching, fainting. If you have them, you may have had a serious allergic reaction to **DIZOVIN**.
- Deep rapid breathing, drowsiness, feeling sick (nausea), being sick (vomiting), stomach pain, weight loss, feeling weak and tired and weakness in the arms and legs. The above side-effects are possible signs of lactic acidosis (severe increase of lactic acid in the blood, liver enlargement, including inflammation (pain and swelling) of the liver and liver failure which can cause death). If you notice these symptoms or if your medical condition has suddenly changed, stop taking **DIZOVIN** and call your doctor immediately. Lactic acidosis is a medical emergency that must be treated in a hospital. Women (including pregnant women), overweight patients, and those who have had lengthy treatment with **DIZOVIN** are more likely to develop lactic acidosis.
- Nausea; stomach pain; low fever; loss of appetite; dark urine; clay-coloured stools; jaundice (yellowing of the skin or eyes) which are signs of liver damage.
- Severe upper stomach pain with nausea (feeling sick) and vomiting which are signs of pancreatitis, a dangerous inflammation of the pancreas and may cause death.

These are all very serious side effects. You may need urgent medical attention or hospitalisation. All of these are very serious side effects and occur less frequently.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Changes in body shape because of changes in fat distribution**.** These changes may include increased amount of fat in the upper back and neck, breast, and around the trunk. Loss of fat from the legs, arms, and face may also happen.
- Chest pain.
- The following blood disorders:
  - Anaemia with symptoms of tiredness, headaches, being short of breath when exercising, dizziness and looking pale.
  - Neutropenia with symptoms of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

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

Tell your doctor if you notice any of the following:
- headaches
- feeling sick (nausea), being sick (vomiting)
- insomnia
- fever
- skin rash (red, raised or itchy skin)
- diarrhoea
- stomach pains, indigestion; loss of appetite; taste disturbance, wind (flatulence)
- feeling dizzy
- aching muscles, general aches and pains
- feeling breathless
- weakness.
- fits (convulsions)
- feeling depressed or anxious; not being able to concentrate; feeling drowsy
- changes in the colour of your nails, your skin, or the skin inside your mouth
- a flu-like feeling — chills, sweating and cough
- tingly feelings in the skin (pins and needles)
- passing urine more often
- enlarged breasts in men.
- side effect that may show up in your blood tests is:
  - an increase in the level of liver enzymes,
  - an increased amount in the blood of *bilirubin* (a substance produced in the liver) which may make your skin appear yellow,
  - a decrease in the number of cells involved in blood clotting *(thrombocytopenia)*, or in all kinds of blood cells *(pancytopenia),*
  - a decrease in the number of a type of red blood cell *(pure red cell aplasia) and* a failure of the bone marrow to produce new blood cells *(aplastic anaemia).*

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

STORING AND DISPOSING OF DIZOVIN:
Store at or below 30 ˚C.
The HDPE containers must be kept tightly closed.
Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION:
DIZOVIN 100 CAPSULES
Round, white HDPE containers with 100 capsules.

DIZOVIN 300 TABLETS:
Round, white HDPE containers with 56 or 60 tablets.

IDENTIFICATION:
DIZOVIN 100 CAPSULES
White to off-white opaque, size 3 capsules, containing white to off-white powder with 'ML21' on cap and '100' on body imprinted with black ink.

DIZOVIN 300 TABLETS
White, circular, biconvex, film coated tablets having 'ML8' debossed on the periphery of one side and plain surface on the other side.

REGISTRATION NUMBER:
DIZOVIN 100: 45/20.2.8/0085
DIZOVIN 300: 45/20.2.8/0086

NAME AND ADDRESS OF REGISTRATION HOLDER:
Macleods Pharmaceuticals SA (Pty) Ltd.
Office block 1, Bassonia Estate Office,
Park (East), 1 Cussonia Drive,
Bassonia Rock, Ext. 12, Alberton.

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Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com/ or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

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INLIGTINGSBLAADJIE VIR PASIËNTE

SKEDULERINGSTATUS: S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
DIZOVIN 100 KAPSULES
DIZOVIN 300 TABLETTE

LEES HIERDIE BLAADJIE NOUKEURIG VOORDAT U BEGIN OM DIZOVIN TE GEBRUIK
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **DIZOVIN** is vir u persoonlik voorgeskryf en u behoort dit nie met ander mense te deel nie. Dit mag hulle skade aandoen, ookal is hul simptome dieselfde.

WAT BEVAT DIZOVIN
DIZOVIN 100 KAPSULES
Elke kapsule bevat sidovudien 100 mg.
Eksipiënte: mikrokristallyne sellulose, mieliestysel, natriumstyselglikolaat, magnesiumstearaat, harde nr. 3 gelatienkapsules, titaandioksied, gelatien, natriumlourielsulfaat.

DIZOVIN 300 TABLETTE
Elke tablet bevat sidovudien 300 mg.
Eksipiënte: mikrokristallyne sellulose, natriumstyselglikolaat, povidoon K 29/32, magnesiumstearaat, kleurstof, Hipromellose, titaandioksied, Macrogol 400.

WAARVOOR WORD DIZOVIN GEBRUIK
DIZOVIN word gebruik om MIV (menslike immuungebrekvirus) infeksie te behandel.
DIZOVIN is 'n tipe medisyne wat bekend staan as 'n anti-retrovirale middel. Dit behoort aan 'n groep medisyne genaamd nukleosied analoog omgekeerde transkriptase remmers (NRTI's). **DIZOVIN** word nie ontslae van MIV-infeksie nie; dit verminder die hoeveelheid virus in jou liggaam en hou dit op 'n lae vlak.
DIZOVIN word, in kombinasie met ander antiretrovirusmiddels, gebruik in die behandeling van MIV in volwassenes en kinders ouer as 12 jaar. Indien u swanger is, mag u dokter voorskryf dat u **DIZOVIN** gebruik om te help dat u nie MIV na u ongebore baba oordra nie. Na geboorte mag u baba orale medisyne ontvang wat sal keer dat u baba met MIV besmet raak.

VOORDAT U DIZOVIN GEBRUIK
Moenie DIZOVIN gebruik nie:
Dit is belangrik dat u u dokter of gesondheidsorgbeampte inlig as u aan enige van die kondisies hieronder genoem, ly en u gebruik DIZOVIN of DIZOVIN is aan u voorgeskryf.
- Indien u hipersensitief (allergies) teen sidovudien of enige van die bestanddele van **DIZOVIN** is.
- Indien u erge allergiese reaksies soos anafilakse of Stevens-Johnson se sindroom (selde voorkomende velkondisie met erge blaasvorming en bloeding van die lippe, oë, mond, neus en geslagsdele) teen enige van die bestanddele van **DIZOVIN** toon.
- Indien u 'n baie lae witbloedseltelling (neutropenie) of 'n baie lae rooibloedseltelling (anemie) het.
- Indien u tans stavudien vir die behandeling van MIV siekte ontvang.
- Kinders jonger as 3 maande oud behoort nie **DIZOVIN** te ontvang nie.

Neem ekstra sorg met DIZOVIN
Sorg behoort aan die dag gelê te word wanneer **DIZOVIN** in die volgende pasiënte gebruik word.
- Indien u ooit aan 'n lewersiekte (insluitende hepatitis B of C) gely het, aangesien die behandeling met **DIZOVIN** in pasiënte met lewersiekte moontlike ernstige newe-effekte wat die lewer aantas, insluitende die dood kan veroorsaak. U dokter sal u lewerfunksie moniteer deur gereelde bloedtoetse uit te voer
- As u aan 'n aanhoudende hepatitis B infeksie ly, moet u nie sonder u dokter se advies met die gebruik van **DIZOVIN** staak nie, aangesien die hepatitis kan terugkeer. Die hepatitis kan ook baie ernstiger wees as u aan 'n ernstige lewersiekte ly.
- Indien u erg oorgewig is (veral vroue).
- Lig u dokter in indien u simptome soos moegheid, hoofpyn, kortademheid met oefening, duiseligheid ondervind en bleek lyk wanneer u **DIZOVIN** gebruik. U mag aan anemie ly, 'n kondisie waar die hoeveelheid suurstofdraende pigment (hemoglobien) in die bloed te min is of waar daar te min rooibloed-selle in die bloed is. U dokter sal u hemoglobien en rooibloedseltelling monitor deur gereeld bloedtoetse uit te voer en indien nodig, die **DIZOVIN** dosis aanpas. Erge gevalle van anemie mag bloedoortappings of onttrekking van **DIZOVIN** vereis.
- Lig u dokter in as u dikwels simptome van infeksie ondervind wanneer u **DIZOVIN** gebruik, soos koors, erge koue rillings, seer keel of mondulkusse. U mag moontlik aan neutropenie, 'n tekort aan witbloedselle, ly. U dokter sal u witbloedseltelling monitor deur gereeld bloedtoetse uit te voer en indien nodig, die **DIZOVIN** dosis aanpas.
- **DIZOVIN** mag spiersiekte (miopatie) en die simptome soos nie-oefeningsverwante spierpyn, spierteerheid of –swakheid veroorsaak.
- Die langtermyn gebruik van **DIZOVIN** mag tot 'n toename in suur in u liggaam lei en tekens van naarheid, braking, buikpyn en –krampe, gewigsverlies, kortademheid of vinnige asemhaling en moegheid veroorsaak. U mag aan 'n kondisie wat melksuurasidose genoem word, ly. Staak die gebruik van **DIZOVIN** en raadpleeg onmiddellik u dokter.
- Neem u kind, indien gedurende swangerskap aan **DIZOVIN** blootgestel is, onmiddellik na u dokter indien hy/sy bleek lyk, swak is, aanhoudend slaperig is, vinniger asemhaal, as die hart vinniger klop, as dit lyk of hy/sy nie gewig aansit nie, as hy/sy braak, koors, seer keel of mondulkusse het, as hy/sy styf is, stuiptrekkings het of abnormale gedrag toon. U dokter sal bykomende mediese en laboratoriumtoetse op u kind doen.
- **DIZOVIN** kan inflammasie van die pankreas verooksaak. Stel u dokter in kennis indien u erge maagpyn ervaar met siekte en braking.
- Vertel jou dokter as jy niersiekte gehad het, of as toetse probleeme met jou niere getoon het. Die dosis van **DIZOVIN** sal moontlik aangepas moet word.
- Vertel jou dokter, indien u veranderinge in u liggaamsvorm en –gewig waarneem, insluitende 'n toename in gewig om die heupe, agter op die nek tussen die skouers, vergroting van die borste of as u gewig in ander dele van u liggaam verloor. **DIZOVIN** kan ook vlakke van suiker en vette (trigliseriede en cholesterol) in die bloed verhoog.
- U mag 'n toename in ander infeksies gedurende die aanvanklike behandeling met **DIZOVIN** in kombinasie met ander antiretrovirusmiddels ondervind as u immuunstelsel beklim is. Mense met gevorderde MIV-infeksie (VIGS) het swak immuunsisteme en is meer geneig tot die ontwikkeling van ernstige infeksies. Wanneer u met behandeling begin, mag u vind dat ou, verborge infeksies opvlam en tekens en simptome van inflammasie veroorsaak. Hierdie simptome word waarskynlik deur die liggaam se immuunsisteem wat sterker word, veroorsaak, sodat die liggaam begin om hierdie infeksies te beveg. Indien u enige simptome van infeksie waarneem, moet u asseblief onmiddellik u dokter daaroor inlig.
- Die langtermyn behandeling met **DIZOVIN** in kombinasie met ander medisyne om MIV te behandel mag osteonekrose (beenafsterwing veroorsaak deur swak bloedtoevoer na die area) veroorsaak. Dit kom mees dikwels in die heup en skouer voor, maar kan ook ander groot gewrigte soos die knie, elmboog, polsgewrig en enkel affekteer.
- **DIZOVIN** is nie 'n genesing vir MIV-infeksie nie. **DIZOVIN** help om u kondisie te beheer en u moet dit elke dag neem om te verhoed dat u siekte erger word. U mag aanhou om ander infeksies en siektes wat met MIV geassosieer word, op te doen. Bly in kontak met u dokter en moenie ophou om **DIZOVIN** te neem sonder om u dokter te raadpleeg nie.
- MIV-infeksie word deur seksuele kontak met iemand wat die infeksie het, versprei, of deur oordraging van besmette bloed (bv. die deel van spuitnaalde). **DIZOVIN** sal nie verhoed dat u MIV-infeksie na ander oordra nie. Om te voorkom dat ander mense met MIV besmet raak:
  - Gebruik 'n kondoom wanneer u orale of penetrerende seks het.
  - Wees versigtig vir bloedoordraging – bv. moenie naalde deel nie.
- Babas van moeders wat **DIZOVIN** ontvang het om die oordraging van MIV van moeder na kind te voorkom, mag anemies raak. Lig u dokter in indien u kind die hele tyd bleek, swak en slaperig is, wanneer hy/sy vinniger begin asemhaal, die hart vinniger klop en dit lyk asof die kind nie gewig wil aansit nie.

Praat met u dokter as enige van hierdie op u van toepassing is. U mag moontlik bykomende doktersbesoeke, insluitende bloedtoetse benodig terwyl u die medikasie gebruik.

Neem van DIZOVIN saam met voedsel en vloeistof:
DIZOVIN kan met of sonder voedsel geneem word.

Swangerskap en borsvoeding:

Indien u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsbeampte raadpleeg voordat u **DIZOVIN** neem.

DIZOVIN kan aan swanger vroue gegee word, vanaf 14 weke van swangerskap tot met die aanvangs van kraam. Swanger vroue wat die gebruik van **DIZOVIN** gedurende swangerskap vir die voorkoming van MIV-oordraging na hul babas oorweeg, moet ingelig word dat oordraging steeds kan plaasvind ten spyte van terapie. Dit word daarom aanbeveel dat moeders wat **DIZOVIN** gebruik, nie hul babas borsvoed nie. Die veiligheid van **DIZOVIN** vir die moeder en die fetus gedurende die eerste drie maande van swangerskap is nie vasgestel nie.
DIZOVIN word in borsmelk uitgeskei.
Weens die potensiaal vir newe-effekte van **DIZOVIN** in hul babas behoort moeders daarom borsvoeding te staak wanneer hulle **DIZOVIN** gebruik. Om die oordraging van MIV na hul babas te vermy, behoort vroue wat met MIV besmet is nie hul babas te borsvoed nie.

Bestuur en die gebruik van masjinerie:
Duiseligheid, ingekorte konsentrasievermoë en lomerigheid is gedurende die gebruik van **DIZOVIN** aangemeld. Indien u hierdie simptome ondervind, behoort u potensieel gevaarlike take soos om motor te bestuur of om met masjinerie te werk, te vermy.

Die gebruik van ander medisyne saam met DIZOVIN:

Laat altyd u gesondheidsbeampte weet as u ander medisyne gebruik (dit sluit komplementêre of tradisionele medisyne in.

DIZOVIN mag die effek van ander medisyne verander, en ander medisyne mag die effek van **DIZOVIN** verander. Wanneer u **DIZOVIN** gebruik, is dit veral belangrik om u dokter of gesondheidsbeampte in te lig indien u enige van die volgende neem:
- Stavudien, gebruik om MIV-besmetting te behandel.
- Rifampisien, 'n antibiotika.

Sommige medisyne mag veroorsaak dat u meer waarskynlik newe-effekte sal ontwikkel, of dat die newe-effekte vererger.
- Valproaat wat gebruik word om epilepsie te behandel.
- Asiklovir, gansiklovir of interferon, wat gebruik word om virusinfeksies te behandel.
- Pirimetamien, wat gebruik word om malaria en ander parasitiese infeksies te behandel.
- Dapsoon, wat gebruik word om longontsteking te voorkom en velinfeksies te behandel.
- Flukonasool of flusitosien, wat gebruik word om swaminfeksies soos *Candida* te behandel.
- Pentamidien of atovakoon, wat gebruik word om parasitiese infeksies soos PCP (pneumosistiese longontsteking) te behandel.
- Probenesied, wat gebruik word om jig te behandel.
- Metadoon wat gebruik word om ernstige pyn te verlig en om onttrekkingsimptome te voorkom in mense wat verslaaf is aan opiate-middels soos heroïen.
- Vinkristien, vinblastien of doksorubisien, wat gebruik word om sekere tipes kanker te behandel.

Lig u dokter in indien u enige van hierdie medisyne gebruik. Sommige medisyne mag 'n interaksie met **DIZOVIN** toon.
Dit sluit die volgende in:
- Klaritromisien, 'n antibiotika.
- Fenitoïen, wat gebruik word om epilepsie te behandel.

Lig u dokter in indien u klaritromisien of fenitoïen neem. U dokter mag u moontlik wil monitor terwyl u **DIZOVIN** gebruik.

HOE OM DIZOVIN TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd DIZOVIN presies soos deur u dokter voorgeskryf. Raadpleeg u dokter of apteker as u onseker is. Indien u van mening is dat die effek van DIZOVIN te sterk of te swak is, moet u u dokter of apteker raadpleeg.

U dokter sal u dosis op grond van u liggaamsgewig, nier- en lewerfunksie bereken, asook enige newe-effek wat u met ander medisyne gehad het. Neem **DIZOVIN** presies soos voorgeskryf is. **DIZOVIN** tablette en kapsules word gewoonlik twee keer per dag (elke 12 ure) geneem. U mag **DIZOVIN** met of sonder voedsel neem.

Swangerskap, geboorte en pasgebore babas:
U behoort gewoonlik nie **DIZOVIN** gedurende die eerste 14 weke van swangerskap te gebruik nie. Na week 14 is die normale dosis 500 mg elke dag in verdeelde dosisse totdat u in kraam gaan. Gedurende kraam en geboorte mag u dokter inspuitings van 'n sidovudien medisyn gee totdat die baba se naelstring afgeklem is. U pasgebore baba mag ook 'n orale oplossing wat sidovudien bevat ontvang wat sal help om te voorkom dat hy/sy nie met MIV besmet word nie.

Mense met nier- of lewerprobleme:
Indien u aan erge nier- of lewerprobleme ly, mag u moontlik 'n laer dosis **DIZOVIN** ontvang, afhangende van hoe goed u niere of lewer funksioneer. Volg u dokter se advies.

As u te veel DIZOVIN gebruik:
Indien u per ongeluk te veel **DIZOVIN** geneem het, moet u onmiddellik mediese hulp kry deur u dokter of gesondheidsbeampte te raadpleeg.

In die geval van oordosering moet u u dokter of apteker raadpleeg. Indien hulle nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

Indien u vergeet om DIZOVIN te neem:
Moenie vergeet om u **DIZOVIN** dosis te neem nie aangesien dit behandeling van die virus moeiliker maak. Indien u 'n dosis oorgeslaan het, neem dit so gou as u daaraan dink. As dit byna tyd vir u volgende dosis is, neem dan slegs die volgende dosis op die geskeduleerde tyd. Moet nooit die dosis verdubbel nie.

MOONTLIKE NEWE-EFFEKTE
DIZOVIN mag newe-effekte veroorsaak.
Nie al die newe-effekte wat vir **DIZOVIN** aangemeld is, word in hierdie blaadjie genoem nie. Indien u algemene gesondheid agteruitgaan terwyl u **DIZOVIN** gebruik, moet u asseblief u dokter, apteker of gesondheidsbeampte vir advies raadpleeg.
Indien enige van die volgende voorkom, moet u met die gebruik van **DIZOVIN** *staak en u dokter onmiddellik raadpleeg, of gaan na die ongevalle afdeling van u naaste hospitaal.*
- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat dit moeilik maak om te sluk of asem te haal, uitslag, jeuk of floute. Indien dit voorkom, mag u moontlik 'n ernstige allergiese reaksie teen **DIZOVIN** getoon het.
- Diep, vinnige asemhaling, lomerigheid, naarheid, braking, maagpyn, gewigsverlies, algemene gevoel van swakheid en moegheid en swakheid in die arms en bene. Die bogenoemde newe-effekte is moontlike tekens van melksuurasidose (erge toename van melksuur in die bloed, lewervergroting, insluitende inflammasie (pyn en swelling) van die lewer en lewerversaking wat die dood kan veroorsaak). Indien u hierdie simptome waarneem of indien u mediese kondisie skielik verander, moet u die gebruik van **DIZOVIN** staak en onmiddellik u dokter ontbied. Melksuurasidose is 'n mediese noodgeval wat in 'n hospitaal behandel moet word. Vroue (insluitende swanger vroue), pasiënte wat oorgewig is en diegene wat reeds lank met **DIZOVIN** behandel word, is meer geneig tot die ontwikkeling van melksuurasidose.
- Naarheid, maagpyn, lae koors, verlies aan eetlus, donker uriene, kleigekleurde stoelgang, geelsug (geel verkleuring van die vel of oë), wat tekens van lewerbeskadiging is.
- Erge boonste maagpyn met naarheid en braking wat tekens van pankreatitis is, 'n gevaarlike inflammasie van die pankreas wat die dood mag veroorsaak.

Hierdie is almal ernstige newe-effekte. U mag moontlik dringende mediese aandag of hospitalisering benodig.
Raadpleeg onmiddellik u dokter of gaan na die ongevalle afdeling van u naaste hospitaal indien u enige van die volgende waarneem:
- Veranderinge in liggaamsvorm weens veranderinge in vetverspreiding. Hierdie veranderinge mag 'n toename in die hoeveelheid vet op die boonste gedeelte van die rug en nek, bors en om die bolyf insluit. Verlies van vet aan die bene, arms en gesig mag ook voorkom.
- Borspyn.
- Die volgende bloedafwykings:
  - Anemie met simptome van moegheid, hoofpyn, kortademheid met oefening, duiseligheid en bleekheid.
  - Neutropenie met simptome van gereelde infeksies soos koors, erge koue rillings, seer keel en mondulkusse

Hierdie is almal ernstige newe-effekte. U mag moontlik ernstige mediese aandag benodig.

Lig u dokter in indien u enige van die volgende waarneem:
- Hoofpyn.
- Naarheid, braking.
- Slaaploosheid.
- Koors.
- Veluitslag (rooi, opgehewe of jeukerige vel).
- Diaree.
- Maagpyn, indigestie, verlies aan eetlus, smaakafwyking, winderigheid.
- Duiseligheid.
- Spierpyn, algemene pyn.
- Kortademheid.
- Swakheid.
- Stuiptrekkings.
- Gevoel van depressie of angs, onvermoë om te konsentreer, lomerigheid.
- Verandering in die kleur van u naels, vel, of die vel aan die binnekant van u mond.
- 'n Griepagtige gevoel, kouer rillings, sweet en hoes.
- Prikkeling van die vel (spelde en naalde).
- Meer gereelde urinering.
- Vergroting van die borste in mans.
- Newe-effekte wat in u bloedtoetse voorkom:
  - Toename in lewerensiemvlakke.
  - Toename van bilirubien in die bloed ('n verbinding wat in die lewer gevorm word) wat u vel 'n geel verkleuring gee.
  - Afname in die aantal selle wat by bloedklontvorming betrokke is (trombositopenie), of 'n afname in alle soorte bloedselle (pansitopenie).
  - Afname in die aantal van 'n sekere tipe rooibloedsel (suiwer rooiselaplasie) en 'n onvermoë van die beenmurg om nuwe rooibloedselle te vorm (aplastiese anemie).

As u enige newe-effekte ondervind wat nie in hierdie blaadjie genoem word nie, moet u asseblief u dokter raadpleeg.

OPBERGING EN WEGDOEN VAN DIZOVIN
Bewaar teen of benede 30 °C.
Die HDPE houers moet dig toe gehou word.
Enige medisyne wat die vervaldatum bereik het of ongebruikte medisyne kan na u naaste apteek teruggeneem word.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS

AANBIEDING
DIZOVIN 100 KAPSULES
Ronde wit HDPE houers met 100 kapsules.

DIZOVIN 300 TABLETTE
Ronde wit HDPE houers met 56 of 60 tablette.

IDENTIFIKASIE
DIZOVIN 100 KAPSULES
Wit tot byna-wit, ondersigtige nr. 3 kapsules met wit tot byna-wit poeier met 'ML21' op die dop en '100' op die liggaam met swart ink gedruk.

DIZOVIN 300 TABLETTE
Wit, ronde, bikonvekse, filmbedekte tablette met 'ML8" op die rand van die een kant gedruk en gladde oppervlakte aan die ander kant.

REGISTRASIENOMMER
DIZOVIN 100 KAPSULES: 45/20.2.8/0085
DIZOVIN 300 TABLETTE: 45/20.2.8/0086

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
Macleods Pharmaceuticals SA (Edms.) Bpk.
Kantoorblok 1
Bassonia Estate Office Park (Oos)
Cussoniarylaan 1
Bassonia Rock, Uitb. 12
Alberton.

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
Datum van registrasie: 7 Desember 2012
Die datum van die mees onlangse hersiene voubiljet soos goedgekeur deur die Raad: 25 November 2016

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Removal of PI as per Latest communication from MA Holder along with Change in the dimensions and inclusion of coating composition as per current MMF.

1. Product : DIZOVIN 100 CAPSULES / DIZOVIN 300 TABLETS	
2. Country: South Africa	**3. Packaging component: Patient Information Leaflet**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 300 (W) mm**
9. Design / Style: NA	**10. Item code No.: PM03079602**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40403 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03079601**
15. Revision no: 01	**16. File Name :Z:\South Africa\Zidovudine\DIZOVIN 300\01\Dizovin PIL - PM03079602.cdr**
Approved By:	**17. Location: Daman**

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
	01/09/2025				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

Format No: FRM/SOP/CO/CQA/021/03-003

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date*
1) New Artwork for South Africa	**PM03079601**	**15/6/19**	
2) Removal of PI as per Latest communication from MA Holder along with Change in the dimensions and inclusion of coating composition as per current MMF.	**PM03079602**		

*Date of Implementation to be filed by plant.