PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LEVUSPOZ 50 AND LEVUSPOZ 100

(powder for solution for infusion)

Micafungin Sodium

Contains sugar: Lactose monohydrate 223,15 mg per vial

Read all of this leaflet carefully before you are given LEVUSPOZ

- 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.

What is in this leaflet

1. What LEVUSPOZ is and what it is used for
2. What you need to know before you are given LEVUSPOZ
3. How to use LEVUSPOZ
4. Possible side effects
5. How to store LEVUSPOZ
6. Contents of the pack and other information

1. What LEVUSPOZ is and what it is used for

LEVUSPOZ contains the active substance micafungin and is available as powder for concentrate for solution for infusion.

LEVUSPOZ is called an antifungal medicine because it is used to treat infections caused by fungal cells.

LEVUSPOZ is used to treat fungal infections caused by fungal or yeast cells called *Candida.*

LEVUSPOZ is effective in treating systemic infections (those that have penetrated within the body). It interferes with the production of a part of the fungal cell wall. An intact cell wall is necessary for the fungus to continue living and growing. LEVUSPOZ causes defects in the fungal cell wall, making the fungus unable to live and grow.

Your doctor has prescribed LEVUSPOZ for you in the following circumstances when there are no other suitable antifungal treatments available (see section 2):

- To treat adults, adolescents and children including neonates who have a serious fungal infection called invasive candidiasis (infection that has penetrated the body).
- To treat adults and adolescents ≥ 16 years of age who have a fungal infection in the gullet (oesophagus) where treatment through injection (intravenous) is appropriate.
- To prevent infection with a bacteria called *Candida* if you are having a bone-marrow transplant or are expected to have a neutropenia (low levels of neutrophils, a type of white blood cell) for 10 days or more.

2. What you need to know before you take LEVUSPOZ

LEVUSPOZ should not be administered to you

- if you are allergic (hypersensitive) to micafungin, other echinocandins or to any of the ingredients in LEVUSPOZ.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have severe liver problems (e.g. liver failure or hepatitis) or have had abnormal liver function tests. During treatment your liver functions will be monitored more closely.
- if you develop severe allergic reaction towards LEVUSPOZ. Symptoms may include rash and rigors (a sudden feeling of cold with shivering accompanied by a rise in temperature). Also inform your doctor if you have underlying conditions such as Advanced AIDS or malignant tumour/ cancer.
- if you develop rash as it may indicate skin problems
- if you have haemolytic anaemia (anaemia due to breakdown of red blood cells) or haemolysis (breakdown of red blood cells). This may be indicated by feeling tired, weakness, irregular heartbeats or shortness of breath.
- if you have kidney problems (e.g. kidney failure and abnormal kidney function test). If this happens, your doctor may decide to monitor your kidney function more closely.

Children and adolescents (below 18 years):

Children may experience more severe side effects than adults. See section 4**.**

Other medicines and LEVUSPOZ

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

It is especially important to inform your doctor if you are using amphotericin B desoxycholate or itraconazole (antifungal antibiotics), sirolimus (medicine used to suppress the immune system) or nifedipine (medicine used to treat high blood pressure) as LEVUSPOZ may increase the blood levels of these medicines in your blood. Your doctor may decide to adjust the dose of these medicines.

LEVUSPOZ with food and drink

As LEVUSPOZ is given intravenously (into a vein), no restrictions on food or drink are required.

Pregnancy, breastfeeding and fertility

You should not receive LEVUSPOZ when you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving this medicine.

Driving and using machines

LEVUSPOZ may cause dizziness and affect the ability to concentrate. Please inform your doctor if you experience any effects that may cause you to have problems with driving or using other machinery.

It is not always possible to predict to what extent LEVUSPOZ may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LEVUSPOZ affects them.

LEVUSPOZ contains Lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before receiving LEVUSPOZ.

3. How to take LEVUSPOZ

You will not be expected to give yourself LEVUSPOZ.
It will be given to you by a person who is qualified to do so.
LEVUSPOZ should be administered once daily by slow intravenous (into a vein) infusion.
Your doctor will determine how much LEVUSPOZ you will receive each day.

Use in adults, adolescents ≥ 16 years of age and elderly

- The usual dose to treat an invasive *Candida* infection is 100 mg per day for patients weighing 40 kg or more and 2 mg/kg per day for patients weighing 40 kg or less.
- The dose to treat a *Candida* infection of the oesophagus is 150 mg for patients weighing more than 40 kg and 3 mg/kg per day for patients weighing 40 kg or less.
- The usual dose to prevent invasive *Candida* infections is 50 mg per day for patients weighing more than 40 kg and 1 mg/kg per day for patients weighing 40 kg or less.

Use in children > 4 months of age and adolescents < 16 years of age

- The usual dose to treat an invasive *Candida* infection is 100 mg per day for patients weighing 40 kg or more and 2 mg/kg per day for patients weighing 40 kg or less.
- The usual dose to prevent invasive *Candida* infections is 50 mg per day for patients weighing more than 40 kg and 1 mg/kg per day for patients weighing 40 kg or less.

Use in children and newborns < 4 months of age

- The usual dose to treat an invasive *Candida* infection is 4-10 mg/kg per day.
- The usual dose to prevent invasive *Candida* infections is 2 mg/kg per day

If you receive more LEVUSPOZ than you should

Since a health care provider will administer LEVUSPOZ, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take LEVUSPOZ

Since a health care provider will administer LEVUSPOZ, it is unlikely that the dose will be missed.

If you stop taking LEVUSPOZ

There are no known withdrawal symptoms.

If you have any further questions on the use of LEVUSPOZ, ask your doctor or pharmacist.

4. Possible side effects

LEVUSPOZ can have side effects.

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

If any of the following happen, stop receiving LEVUSPOZ 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
- severe skin reaction (e.g. blistering and peeling of the skin) rash
- fainting and shock
- severe condition of the skin that may affect the mouth and other parts of the body (erythema multiforme)
- rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens- Johnson syndrome)
- sudden life-threatening allergic reaction (Anaphylactoid shock)

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

- changes in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing
- signs of frequent infections such as fever or sore throat

- less urine than is normal for you
- yellowing of the skin and eyes, also called jaundice
- liver damage/disease (hepatocellular damage including fatal cases)

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

Frequent side effects:

Tell your doctor if you notice any of the following:

- nausea (feeling sick), vomiting
- stomach pains
- headache
- diarrhoea
- Fever
- shivering
- decreased white blood cell (Leukopenia/ Neutropenia)
- decreased number of red blood cells (Anaemia)
- low potassium levels in the blood (Hypokalaemia)
- low magnesium levels in the blood (Hypomagnesaemia)
- low calcium levels in the blood (Hypocalcaemia)
- increased blood alkaline phosphatase, which may have symtops such as dark-colored urine and/or light-colored stool, swelling and pain in your stomach, itching or nausea and vomiting
- increased aspartate aminotransferase or increased alanine aminotransferase which may have symptoms such as swelling in your ankles and legs, tiredness, nausea and vomiting, weight loss or dark-colored urine

- increased blood bilirubin (including hyperbilirubinaemia), which may have symptoms such as abdominal pain or swelling, chills, fever, chest pain, weakness, lightheadedness, fatigue and nausea.
- abnormal liver function test

Less frequent side effects:

- dizziness
- loss of appetite
- inflammation at the injection site
- increased sweating
- difficulty in sleeping
- anxiety
- disturbed taste
- increase or decrease in blood pressure (Hypotension or Hypertension)
- low blood platelet count (Thrombocytopenia)
- a decrease in albumin in the blood, causing water retention (Hypoalbuminaemia)
- low sodium levels in the blood (Hyponatraemia)
- high potassium levels in the blood (Hyperkalaemia)
- low phosphate levels in the blood (Hypophosphataemia)
- reddening of your skin called flushing
- increased blood lactate dehydrogenase, which usually means you have some type of tissue damage or disease

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 LEVUSPOZ.

5. How to store LEVUSPOZ

Store at or below 30 °C.

Protect from light.

Store in original package.

Store all medicines out of reach of children.

Do not use LEVUSPOZ after the expiry date which is stated on the vial and on the carton. The expiry date refers to the last day of that month.

The unopened vial does not require any special storage conditions.

The reconstituted concentrate and the diluted infusion solution should be used immediately.

Do not use the diluted infusion solution if it is cloudy or precipitated.

In order to protect the infusion bottle / bag containing the diluted infusion solution from light it should be inserted into a closable opaque bag.

The vial is for single use only. Therefore, please discard unused reconstituted concentrate immediately.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Reconstituted LEVUSPOZ should be used immediately because it does not contain any preservatives to prevent bacterial contamination. Only a trained health care professional who has read the complete directions properly can prepare LEVUSPOZ for use.

6. Contents of the pack and other information

What LEVUSPOZ contains

The active substance is Micafungin.

The other ingredients are lactose monohydrate (low endotoxin), citric acid, sodium hydroxide (as solution 0,1 %), water for Injection and nitrogen.

What LEVUSPOZ looks like and contents of the pack

LEVUSPOZ 50 and 100:

One or 5 clear, amber glass vials with a rubber stopper and aluminium closure with red or blue plastic disc, containing solid white to off white powder, packed in a carton box together with the leaflet.

Holder of Certificate of Registration

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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

LEVUSPOZ 50 EN LEVUSPOZ 100

(poeier vir oplossing vir infusie)

Natriummikafungin

Bevat suiker: Laktosemonohidraat 223,15 mg per flessie

Lees hierdie hele inligtingstuk noukeurig deur voordat LEVUSPOZ aan jou toegedien word

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgvoorsiener

Wat is in hierdie inligtingstuk

1. Wat is LEVUSPOZ en waarvoor word dit gebruik
2. Wat jy moet weet voordat LEVUSPOZ aan jou toegedien word
3. Hoe om LEVUSPOZ te gebruik
4. Moontlike newe-effekte
5. Hoe om LEVUSPOZ te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat is LEVUSPOZ en waarvoor word dit gebruik

LEVUSPOZ bevat die aktiewe bestanddeel, mikafungin en is beskikbaar as poeier vir konsentraat vir oplossing vir infusie.

LEVUSPOZ word ‘n antifungusmiddel genoem omdat dit gebruik word om infeksies te behandel wat deur fungusselle veroorsaak word.

LEVUSPOZ word gebruik om fungusinfeksies te behandel wat deur fungus- of gisselle, wat *Candida* genoem word, veroorsaak word.

LEVUSPOZ is effektief in die behandeling van sistemiese infeksies (dié wat die liggaam binnegedring het). Dit meng in met die produksie van ‘n gedeelte van die fungus se selwand. ‘n Ongeskonde selwand is nodig vir die fungus om voort te leef en te groei. LEVUSPOZ veroorsaak gebreke in die fungusselwand wat dit onmoontlik maak vir die fungus om te oorleef en te groei.

Jou dokter het LEVUSPOZ in die volgende omstandighede vir jou voorgeskryf wanneer daar geen ander geskikte antifungusbehandelings beskikbaar is nie (sien afdeling 2):

- Om volwassenes, adolessente en kinders insluitend pasgeborenes, wat ‘n ernstige fungusinfeksie wat indringende kandidiase genoem word (infeksie wat die liggaam binnegedring het) het, te behandel.
- Om volwassenes en adolessente ≥ 16-jarige ouderdom wat ‘n fungusinfeksie in die slukderm (esofagus) het, waar behandeling deur inspuiting (intraveneus) toepaslik is, te behandel.
- Om infeksie met ‘n bakterie wat *Candida* genoem word, as jy ‘n beenmurgoorplanting het of vermoed word om ‘n neutopenie (lae vlakke van neutrofiele, ‘n tipe witbloedsel) vir 10 of meer dae te hê, te voorkom.

2. Wat jy moet weet voordat LEVUSPOZ aan jou toegedien word

LEVUSPOZ moet nie aan jou toegedien word nie

- as jy allergies (hipersensitief) is vir mikafungin, ander ekinokandiene of vir enige van die bestanddele in LEVUSPOZ.
- as jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgvoorsiener in voordat die inspuiting aan jou toegedien word:

- as jy ernstige lewerprobleme het (bv. lewerversaking of hepatitis) of abnormale lewerfunksietoetse gehad het. Tydens behandeling, sal jou lewerfunksies noukeurig gemonitor word.
- as jy ernstige allergiese reaksie teenoor LEVUSPOZ ontwikkel. Simptome kan uitslag en koudheid (‘n skielike koue gevoel met bewing gepaardgaande met ‘n verhoogde koors) insluit. Lig jou dokter ook in as jy onderliggende toestande soos gevorderde VIGS of kwaadaardige gewas/kanker het.
- as jy uitslag ontwikkel aangesien dit ‘n aanduiding van velprobleme kan wees
- as jy hemolitiese anemie het (anemie as gevolg van die afbraak van rooibloedselle) of hemolise (afbraak van rooibloedselle). Dit kan aangedui word deur moeë gevoel, swakheid, onreëlmatige hartkloppings of kortasemigheid.
- as jy nierprobleme het (bv. nierversaking en abnormale nierfunksietoetse). Indien dit gebeur, mag jou dokter besluit om jou nierfunksie meer noukeurig te monitor.

Kinders en adolessente (onder 18-jarige ouderdom):

Kinders kan meer ernstige newe-effekte as volwassenes ervaar. Sien afdeling 4**.**

Ander medisyne en LEVUSPOZ

Lig jou gesondheidsorgvoorsiener altyd in as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

Dit is veral belangrik om jou dokter in te lig as jy amfoterisien-B desoksicholaat of itrakonasool (antifungus-antibiotika), sirolimus (medisyne wat gebruik word om die immuunstelsel te onderdruk) of nifedipien (medisyne wat gebruik word om hoë bloeddruk te behandel) gebruik, aangesien LEVUSPOZ die bloedvlakke van hierdie medisyne in jou bloed kan verhoog. Jou dokter mag besluit om die dosis van hierdie medisyne aan te pas.

LEVUSPOZ saam met voedsel en drinkgoed

Aangesien LEVUSPOZ intraveneus (binne-in ‘n aar) toegedien word, is geen beperkings op voedsel en drinkgoed nodig nie.

Swangerskap, borsvoeding en vrugbaarheid

LEVUSPOZ moet nie aan jou toegedien word as jy swanger is of jou baba borsvoed nie. As jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om ‘n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgvoorsiener raadpleeg vir advies voordat hierdie medisyne aan jou toegedien word.

Bestuur en gebruik van masjinerie

LEVUSPOZ kan duiseligheid veroorsaak en die vermoë om te konsentreer affekteer. Lig asseblief jou dokter in as jy enige effekte ervaar wat kan veroorsaak dat jy probleme het met bestuur en gebruik van ander masjinerie.

Dit is nie altyd moontlik om te voorspel tot watter mate LEVUSPOZ met die daaglikse aktiwiteite van ‘n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie betrokke raak in die bogenoemde aktiwiteite totdat hulle bewus is van die mate waartoe LEVUSPOZ hulle affekteer nie.

LEVUSPOZ bevat laktosemonohidraat

As jy deur jou dokter ingelig is dat jy ‘n onverdraagsaamheid teenoor sommige suikers het, moet jy jou dokter raadpleeg voordat LEVUSPOZ aan jou toegedien word.

3. Hoe om LEVUSPOZ te gebruik

Daar word nie van jou verwag om LEVUSPOZ aan jouself toe te dien nie.
Dit sal deur ‘n gekwalifiseerde persoon aan jou toegedien word.
LEVUSPOZ moet een keer per dag deur stadige intraveneuse (binne-in die aar) infusie toegedien word. Jou dokter sal bepaal hoeveel LEVUSPOZ jy elke dag sal ontvang.

Gebruik in volwassenes, adolessente ≥ 16-jarige ouderdom en bejaardes

- Die normale dosis om ‘n indringende *Candida*-infeksie te behandel, is 100 mg per dag vir pasiënte wat 40 kg of meer weeg en 2 mg/kg per dag vir pasiënte wat 40 kg of minder weeg.

- Die dosis om 'n *Candida*-infeksie van die esofagus te behandel, is 150 mg vir pasiënte wat meer as 40 kg weeg en 3 mg/kg per dag vir pasiënte wat 40 kg of minder weeg.
- Die normale dosis om indringende *Candida*-infeksies te voorkom, is 50 mg per dag vir pasiënte wat meer as 40 kg weeg en 1 mg/kg per dag vir pasiënte wat wat 40 kg of minder weeg.

Gebruik in kinders > ouderdom van 4 maande en adolessente < 16-jarige ouderdom

- Die normale dosis om indringende *Candida*-infeksies te behandel, is 100 mg per dag vir pasiënte wat 40 kg of meer weeg en 2 mg/kg per dag vir pasiënte wat 40 kg of minder weeg.
- Die normale dosis om indringende *Candida*-infeksies te voorkom, is 50 mg per dag vir pasiënte wat meer as 40 kg weeg en 1 mg/kg per dag vir pasiënte wat 40 kg of minder weeg.

Gebruik in kinders en pasgeborenes < ouderdom van 4 maande

- Die normale dosis om indringende *Candida*-infeksie te behandel, is 4-10 mg/kg per dag.
- Die normale dosis om indringende *Candida*-infeksies te voorkom, is 2 mg/kg per dag.

As jy meer LEVUSPOZ ontvang het as wat jy behoort te ontvang

Aangesien die gesondheidsorgvoorsiener LEVUSPOZ sal toedien, sal hy/sy die dosis kontrolleer. In die geval van oordosering, sal jou dokter egter die oordosering bestuur.

As jy vergeet het om LEVUSPOZ te neem

Aangesien die gesondheidsorgvoorsiener LEVUSPOZ sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

As jy ophou om LEVUSPOZ te ontvang

Daar is geen bekende onttrekkingsimptome nie.

Vra jou dokter of apteker as jy enige verdere vrae het oor die gebruik van LEVUSPOZ.

4. Moontlike newe-effekte

LEVUSPOZ kan newe-effekte hê.

Nie alle newe-effekte wat vir LEVUSPOZ aangemeld word, is in hierdie inligtingstuk ingesluit nie. Indien jou algemene gesondheid verswak of as jy enige ongewenste effekte ervaar terwyl jy LEVUSPOZ ontvang, moet jy asseblief jou gesondheidsorgvoorsiener raadpleeg vir advies.

Indien enige van die volgende gebeur, moet jy ophou om LEVUSPOZ te ontvang en moet jy jou dokter onmiddellik inlig of na die ongevalle afdeling by jou naaste hospitaal gaan:

- swelling van die hande, voete, enkels, gesig, lippe, mond, of keel wat probleme om te sluk of asem te haal kan veroorsaak
- ernstige velreaksie (bv. blasievorming en afskilfering van die vel) uitslag
- floute en skok
- ernstige toestand van die vel wat die mond en ander dele van die liggaam kan affekteer (veelvuldige eriteem)
- seldsame veltoestand met ernstige blasies en bloeding in die lippe, oë, mond, neus en geslagsdele (Stevens- Johnson se sindroom)
- skielike lewensbedreigende allergiese reaksie (anafilaktoïede skok)

Hierdie is almal baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige allergiese reaksie teen LEVUSPOZ gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:

- veranderinge in die manier waarop jou hart klop, byvoorbeeld, as jy opmerk dat dit vinniger klop
- asemhalingsprobleme
- tekens van dikwelse infeksies soos koors of seerkeel
- minder urine as wat normaal vir jou is
- vergeling van die vel en oë, ook geelsug genoem
- lewerskade/siekte (hepatosellulêre skade insluitend noodlottige gevalle)

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Dikwelse newe-effekte:

Lig jou dokter in as jy enige van die volgende opmerk:

- naarheid (voel mislik), braking
- maagpyne
- hoofpyn
- diaree
- koors
- bewerigheid
- afname in die aantal witbloedselle (leukopenie/neutropenie)

- afname in die aantal rooibloedselle (anemie)
- lae kaliumvlakke in die bloed (hipokalemie)
- lae magnesiumvlakke in die bloed (hipomagnesemie)
- lae kalsiumvlakke in die bloed (hipokalsemie)
- verhoogde bloed alkaliese fosfatase, wat simptome soos donkergekleurde urine en/of liggekleurde stoelgange, swelling en pyn op jou maag, jeukerigheid of naarheid en braking kan veroorsaak
- verhoogde aspartaat-aminotransferase of verhoogde alanien-amino-transferase wat simptome soos swelling van jou enkels en bene, moegheid, naarheid en braking, gewigsverlies of donkergekleurde urine veroorsaak
- verhoogde bloedbilirubien (insluitend hiperbilirubinemie), wat simptome soos abdominale pyn of swelling, koue rillings, koors, borskaspyn, swakheid, lighoofdigheid, moegheid en naarheid kan veroorsaak.
- abnormale lewerfunksietoets

Minder dikwelse newe-effekte:

- duiseligheid
- verlies aan aptyt
- inflammasie by die inspuitingsplek
- verhoogde sweet
- probleme om te slaap
- angstigheid
- versteurde smaak
- verhoging of verlaging van bloeddruk (hipotensie of hipertensie)
- lae bloedplaatjie-telling (trombositopenie)

- ‘n afname in albumien in die bloed, wat vogretensie veroorsaak (hipoalbuminemie)
- lae natriumvlakke in die bloed (hiponatremie)
- hoë kaliumvlakke in die bloed (hiperkalemie)
- lae fosfaatvlakke in die bloed (hipofosfatemie)
- rooi verkleuring van jou vel wat blosing genoem word
- verhoogde bloedlaktaatdehidrogenase, wat gewoonlik beteken dat jy ‘n sekere tipe van weefselbeskadiging of siekte het.

As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet jy asseblief jou dokter of apteker inlig.

Aanmelding van newe-effekte

Lig jou dokter, apteker of verpleegkundige in as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA *via* die “6.04 Adverse Drug Reaction Reporting Form” aanmeld, wat aanlyn onder SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van LEVUSPOZ te voorsien.

5. Hoe om LEVUSPOZ te bewaar

Bewaar by of benede 30 °C.

Beskerm teen lig.

Bewaar in die oorspronklike verpakking.

Bewaar alle medisyne buite die bereik van kinders.

Moenie LEVUSPOZ na die vervaldatum, soos aangedui op die flessie en op die karton, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Die onoopgemaakte flessie benodig nie enige spesiale bewaringstoestande nie.

Die hersaamgestelde konsentraat en die verdunde infusie-oplossing moet onmiddellik gebruik word.

Moenie die verdunde infusie-oplossing gebruik as dit troebel is of gepresipiteer het nie.

Ten einde die infusiebottel/sak wat die verdunde infusie-oplossing bevat teen lig te beskerm, moet dit in ‘n ondeursigtige sak wat toegemaak kan word, geplaas word.

Die flessie is slegs vir enkelgebruik. Vernietig asseblief daarom ongebruikte hersaamgestelde konsentraat onmiddellik.

Daar moet nie van medisyne *via* afvalwater of huishoudelike afval ontslae geraak word nie. Vra jou apteker hoe om van medisyne wat nie langer benodig word nie, ontslae te raak. Hierdie maatreëls sal help om die omgewing te beskerm.

Hersaamgestelde LEVUSPOZ moet onmiddellik gebruik word omdat dit geen preserveermiddels bevat om bakteriële kontaminasie te voorkom nie. Slegs ‘n opgeleide gesondheidsorgvoorsiener wat die volledige aanwysings behoorlik gelees het, kan LEVUSPOZ voorberei vir gebruik.

6. Inhoud van die verpakking en ander inligting

Wat LEVUSPOZ bevat

Die aktiewe bestanddeel is mikafungin.

Die ander bestanddele is laktosemonohidraat (lae endotoksien), sitroensuur, natriumhidroksied (as 0,1 % oplossing), water vir inspuiting en stikstof.

Hoe LEVUSPOZ lyk en inhoud van die verpakking

LEVUSPOZ 50 en 100:

5 helder, amber-glasflessies met ‘n rubberprop en aluminiumseël met ‘n rooi of blou plastiekdoppie, bevattende soliede wit tot naaswit poeier, verpak in ‘n kartondosie saam met die inligtingstuk.

Houer van die Registrasiesertifikaat

RANBAXY PHARMACEUTICAL (PTY) LTD

‘n Sun Pharma maatskappy

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Roodepoort, Johannesburg,

1724

Hierdie inligtingstuk was laas hersien in

Aansoeknommer

To be allocated