Patient Information Leaflet

SCHEDULING STATUS:

S4

TERISOM (intravenous infusion 50 mg / vial)

Amphotericin B

Contains sugar (lactose monohydrate)

TERISOM contains 900 mg sucrose per via

Read all of this leaflet carefully before you are given TERISOM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

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

1. What TERISOM is and what it is used for.

TERISOM contains an antifungal antibiotic amphotericin B, which is a medicine used to treat the following serious infections caused by fungi.

- Fungal infections of one or more deep organs of the body.
- Suspected fungal infections in patients with a raised temperature and neutropenia. Neutropenia is a reduced number of white blood cells called

Initial:
Date: 19 July 2023

neutrophils. These are important in fighting infections. Neutropenia can be a side effect of cancer treatments.

- Visceral leishmaniasis, a disease caused by a parasite

2. What you need to know before TERISOM is given to you

TERISOM should not be administered to you:

- If you are hypersensitive (allergic) to the active ingredient amphotericin B or any of the other ingredients of this product. Allergic reaction symptoms including flushing, itching, sickness, swelling of the face, mouth, tongue, and airways, often enough to cause difficulty breathing.
- If you are pregnant or breastfeeding as safety in pregnancy and lactation has not been established.

Warnings and precautions

Talk to your doctor or healthcare provider before being given TERISOM:

Special care should be taken with TERISOM:

- If you have a severe allergic (anaphylaxis and anaphylactoid) reaction. If this happens your doctor will stop the infusion.
- If you experience other reactions that are thought to be related to the infusion. If this happens, your doctor might slow down the infusion, so you will receive **TERISOM** over a longer period of time (approximately 2 hours). Your doctor may also give you medicines to prevent or treat infusion-related reactions, such as diphenhydramine (an antihistamine), paracetamol, pethidine (for pain relief), and/or hydrocortisone (an anti-inflammatory medicine that works by reducing the response of your immune system).

- If you are taking other medicines that may cause kidney damage. **TERISOM** may cause damage to the kidneys. Your doctor will take regular samples to test creatinine (a chemical in the blood that reflects kidney function) and electrolyte levels (particularly potassium and magnesium) which can be abnormal due to reduced kidney function. The blood samples will also be tested for changes in your liver, and your body's ability to produce new blood cells and platelets.
- If you are receiving or have just received a leukocyte (white blood cell) transfusion. Sudden and severe problems in the lungs can happen if you are given **TERISOM** infusion during or shortly after a white blood cell transfusion. Your doctor will recommend that the infusions are separated by as long a period as possible. This will reduce the risk of lung problems, and your lungs will be monitored.
- If you are diabetic because **TERISOM** contains approximately 900 mg of sucrose in each vial.
- If the results of your blood tests show a change in kidney function or other important changes.

Children and adolescents

TERISOM has been used to treat children aged from 1 month to 18 years old. **TERISOM** has not been studied in babies under one month old.

Other medicines and TERISOM:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines). If they are taken with **TERISOM** their effect or the effect of **TERISOM** may cause undesirable interactions. In particular, tell your doctor or pharmacist if you are taking any of the following medicines.

Medicines that may cause kidney damage, including:

- Medicines that suppress the immune system (immunosuppressants) such as cyclosporine
- Any of the group of antibiotics known as aminoglycosides, including gentamycin, neomycin and streptomycin.
- Pentamidine (antimicrobial medication).

Medicines that may lower your potassium levels:

- Corticosteroids (anti-inflammation medicines that work by reducing the response of your immune system) and corticotrophin, used to control the amount of corticosteroid produced by your body.
- Diuretics, medicines that increase the amount of urine your body produces, for example furosemide.
- Digitalis glycosides used to treat heart failure. **TERISOM** may worsen the side effects of digitalis, such as heart rhythm changes.
- Skeletal muscle relaxants, usually used during surgery, such as tubocurarine. **TERISOM** may increase the muscle relaxant effect.

Other medicines:

- Antifungals such as flucytosine. **TERISOM** may worsen the side effects of flucytosine
- Anticancer medicines such as methotrexate, doxorubicin, carmustine and cyclophosphamide. Taking this type of medicine with **TERISOM** may cause kidney damage, wheezing or trouble breathing and low blood pressure.
- White blood cell (Leukocyte transfusions). Sudden and severe problems in the lungs can happen if you are given **TERISOM** infusion during or shortly after a

white blood cell transfusion. Your doctor will recommend that the infusions are separated by as long a period as possible. This will reduce the risk of lung problems and your lungs will be monitored

TERISOM *with food drink and alcohol:*

No interaction has been reported with food, drink and alcohol.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before receiving this medicine.

The safety of **TERISOM** during pregnancy is not known

Breast-feeding

If you are breast-feeding, tell your doctor. You should not breast-feed during treatment with **TERISOM.**

Driving and using machinery:

Do not drive or operate machinery.

Some of the possible side effects of **TERISOM** could affect your ability to drive or use machines safely, See Section 4, Possible side effects.

TERISOM contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before **TERISOM** is administered.

3. How to use TERISOM:

TERISOM is always given to you by a doctor or nurse. The dosage of **TERISOM** is dependent on body weight and is adjusted to meet the needs of each individual patient. Your doctor will decide on the appropriate dosage for you.

Suspected fungal infections:

The recommended daily dose is 3 mg per kg of body weight, per day.

Fungal infections of one or more deep organs of the body:

The recommended daily dose is 3-5 mg per kg of body weight, per day. The duration of therapy will be determined on an individual basis by your Doctor.

Fungal infection of the tissues covering the brain and spinal cord (Cryptococcal meningitis)

The recommended daily dose is 6 mg per day.

Visceral leishmaniasis:

The recommended daily dose is 3 - 4 mg/day.

Your doctor will decide on the amount of **TERISOM** you will receive and over how many days it will be given.

Children

TERISOM has been used to treat children aged from 1 month to 18 years old.

TERISOM has not been studied in babies under 1 month old.

Elderly

No change in dose or frequency of infusion is required for elderly patients.

Patients with reduced kidney function:

No change in dose or frequency of infusion is required. Your doctor will take regular blood samples to test for changes in kidney function.

If you have the impression that the effect of **TERISOM** is too strong or too weak, talk to your doctor or pharmacist. The dose will be controlled in regular intervals by your doctor and adapted if necessary.

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

Method of administration:

To prepare the infusion **TERISOM** must be dissolved in sterile water for injection and then diluted with a solution containing dextrose.

TERISOM must not be mixed with saline (salt) solutions or with other medicinal products or electrolytes.

If you receive a higher dose of **TERISOM** than you should:

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

If you forget to use **TERISOM**:

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

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

4. Possible side effects

TERISOM can have side effects.

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

If you notice any of the following happens, tell your doctor immediately:

- A severe, potentially life-threatening allergic reaction (anaphylactic reactions)
- A pink or red rash with or without pus-filled bumps or blisters, scaly, flaky skin, fever, facial swelling, swollen or tender lymph nodes, swollen saliva glands, dry mouth (Hypersensitivity reaction)

These are all very serious side effects. If you have them, you may have had a serious reaction to **TERISOM**. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- Difficulty in breathing, wheezing or coughing (bronchospasm)
- A condition in which there is a decreased number of red blood cells (anaemia)
- Heart attack (cardiac arrest)
- Painless swelling under the skin (angioneurotic oedema)

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:

- Low potassium levels in the blood (Hypokalaemia)
- Low magnesium levels in the blood (Hypomagnesaemia)
- Low calcium levels in the blood (hypocalcaemia)
- High sugar (glucose) levels in the blood (hyperglycaemia)

- low sodium levels in the blood (hyponatraemia)
- Headache
- Fast heart beat (Tachycardia)
- Widening of blood vessels (Vasodilation)
- Flushing
- Low blood pressure (Hypotension)
- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain
- Your liver is inflamed (Liver function test abnormal)
- Abnormally high levels of bilirubin (hyperbilirubinaemia)
- Increased liver enzyme (Alkaline phosphatase increased).
- Increased creatinine
- Blood urea increased
- Rash
- Back pain
- Fever or high temperature (pyrexia)
- A sudden feeling of cold with shivering accompanied by a rise in temperature (rigors)
- Chest pain

Less frequent side effects:

- Low blood platelet count (Thrombocytopenia)
- Convulsion

- Changes in the way the heart beats (arrhythmia)
- Kidney disease where you pass little or no urine (renal failure)
- Poor function of the kidneys (renal insufficiency)
- A breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolosis)
- Joint pain (arthralgia)

Side effects during the infusion

Frequent side effects: fever, chills, and shivering.

Less frequent infusion-related side effects include: chest tightness, chest pain, breathlessness, difficulty breathing (possibly with wheezing), flushing, a faster heart rate than normal, low blood pressure and musculoskeletal pain (described as joint pain, back pain, or bone pain).

These side effects clear up quickly when the infusion is stopped. These reactions may not happen with future infusions of **TERISOM** or with a slower infusion (over 2 hours). Your doctor may give you other medicines to prevent infusion-related reactions, or to treat the symptoms if you do get them. If you have a severe infusion-related reaction, your doctor will stop the **TERISOM** infusion and you should not receive this treatment in the future. 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 **TERISOM**.

5. How to store TERISOM

TERISOM unopened vials:

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use this medicine after the expiry date stated on the carton.

6. Contents of the pack and other information

What TERISOM contains

Distearoylphosphatidyl glycerol, Hydrogenated soya phosphatidylcholine, Cholesterol NF, Alpha-Tocopherol USP, Sucrose NF, Sodium succinate dibasic hexahydrate.

What TERISOM looks like and contents of the pack

Yellow lyophilised cake or powder, free of visible evidence of contamination.

Reconstituted solution: Yellow coloured suspension free from visible foreign particulate matter.

TERISOM is presented in 15 ml, 20 ml or 30 ml sterile, Type I glass vials. The closure consists of a grey butyl rubberstopper and aluminium ring seal fitted with a removable plastic cap. Single-dose vials are packed ten per carton with 10 filters. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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Roodepoort, 1724

This leaflet was last revised in

Registration numbers

56/20.2.2/1125

Initial:
Date: 19 July 2023

Pasiëntinligtingstuk

SKEDULERINGSTATUS:

S4

TERISOM (intraveneuse infusie 50 mg / flessie)

Amfoterisien-B

Bevat suiker (laktosemonohidraat)

TERISOM bevat 900 mg sukrose per flessie

Lees die hele inligtingstuk noukeurig deur voordat TERISOM aan jou toegedien word

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

Wat is in hierdie inligtingstuk

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

1. Wat is TERISOM en waarvoor word dit gebruik.

TERISOM bevat ‘n antifungus-antibiotikum, amfoterisien-B, wat ‘n medisyne is wat gebruik word om die volgende ernstige infeksies wat deur fungi veroorsaak word, te behandel.

- Fungusinfeksies van een of meer van die diep organe van die liggaam.
- Vermoedelike fungusinfeksies in pasiënte met ‘n verhoogde koors en neutropenie. Neutropenie is ‘n verminderde aantal witbloedselle wat neutrofiele

genoem word. Hierdie is belangrik om infeksies te beveg. Neutropenie kan ‘n newe-effek wees van kankerbehandelings.

- Ingewands-leishmaniase, ‘n siekte wat deur ‘n parasiet veroorsaak word.

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

TERISOM moet nie aan jou toegedien word:

- As jy hipersensitief (allergies) is vir die aktiewe bestanddeel, amfoterisien-B of enige van die ander bestanddele van die produk nie. Allergiese reaksie-simptome sluit blosing, gejeuk, mislikheid, swelling van die gesig, mond, tong, en lugweë, soms genoeg om moeilike asemhaling te veroorsaak, in.
- As jy swanger is of borsvoed, aangesien veiligheid in swangerskap en laktasie nie vasgestel is nie.

Waarskuwings en voorsorgmaatreëls

Praat met jou dokter of gesondheidsorgvoorsiener voordat TERISOM aan jou toegedien word:

Spesiale sorg moet toegepas word met TERISOM:

- As jy ‘n ernstige allergiese (anafilakse en anafilaktoïede) reaksie het. As dit gebeur, sal jou dokter dadelik die infusie staak.
- As jy ander reaksies ervaar wat vermoed word om verwant te wees aan die infusie. As dit gebeur, mag jou dokter die infusie stadiger stel, sodat jy **TERISOM** oor ‘n langer tydperk (ongeveer 2 uur) ontvang. Jou dokter mag ook medisyne aan jou toedien wat infusie-verwante reaksies kan voorkom of behandel, soos difenhidramien (‘n antihistamien), parasetamol, petidien (vir pynverligting), en/of hidrokortisoon (‘n anti-inflammatoriese medisyne wat werk deur die respons op jou immuunstelsel te verlaag).

- As jy ander medisyne gebruik wat nierskade kan veroorsaak. **TERISOM** kan skade aan die niere veroorsaak. Jou dokter sal gereëlde monsters neem om kreatinien (‘n chemikalie in die bloed wat nierfunksie weerspieël) en elektrolietvlakke (veral kalium en magnesium) te toets wat abnormaal kan wees as gevolg van afname in nierfunksie. Die bloedmonsters sal ook getoets word vir veranderinge in jou lewer, en jou liggaam se vermoë om nuwe bloedselle en plaatjies te vervaardig.
- As jy ‘n leukosiet- (witbloedsel) infusie ontvang of nou net ontvang het. Skielike en ernstige probleme in die longe kan gebeur as **TERISOM-**infusie tydens of kort na ‘n witbloedselinfusie aan jou toegedien word. Jou dokter sal aanbeveel dat die infusies vir so lang periode as moontlik van mekaar toegedien word. Dit sal die risiko van longprobleme verlaag, en jou longe sal gemonitor word.
- As jy diabeties is, omdat **TERISOM** ongeveer 900 mg sukrose in elke flessie bevat.
- As die uitslag van jou bloedtoetse ‘n verandering in nierfunksie of ander belangrike veranderinge toon.

Kinders en adolessente

Amfoterisien-B, soos in **TERISOM,** is in pediatriese pasiënte van ouderdom een maand tot 18-jaar oud bestudeer. Die veiligheid en doeltreffendheid van amfoterisien-B, soos in **TERISOM,** is nie vasgestel in suigelinge onder die ouderdom van een maand nie.

Ander medisyne en TERISOM:

Lig jou gesondheidsorgvoorsiener altyd in as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in). As hulle saam met **TERISOM** geneem word, kan hulle effek of die effek van **TERISOM** ongewenste interaksies veroorsaak.

Lig jou dokter of apteker veral in as jy enige van die volgende medisyne gebruik.

Medisyne wat nierskade kan veroorsaak, insluitend:

- Medisyne wat die immuunstelsel onderdruk (immuunonderdrukkers) soos siklosporien
- Enige van die groep van antibiotika bekend as aminoglikosiede, insluitend gentamisien, neomisien en streptomisien.
- Pentamidien (antimikrobiese medikasie).

Medisyne wat jou kaliumvlakke kan verlaag:

- Kortikosteroïede (anti-inflammatoriese medisyne wat werk deur verlaging van die respons op jou immuunstelsel) en kortikotropien, gebruik om die hoeveelheid van kortikosteroïed wat deur jou liggaam geproduseer word, te beheer.
- Diuretika, medisyne wat die hoeveelheid urine wat deur jou liggaam geproduseer word, te verhoog, byvoorbeeld furosemied.
- Digitalisglikosiede wat gebruik word om hartversaking te behandel. **TERISOM** kan die newe-effekte van digitalis vererger, soos hartritme-veranderinge.
- Skeletspierverslappers, gewoonlik gebruik tydens chirurgie, soos tubokurarien. **TERISOM** kan die spierverslappingseffek verhoog.

Ander medisyne:

- Antifungus middels soos flusitosien. **TERISOM** kan die newe-effekte van flusitosien vererger.
- Antikanker-medisyne soos metotreksaat, doksorubisien, karmustien en siklofosfamied. Die neem van hierdie soort medisyne saam met **TERISOM** kan nierskade, hyging of probleme met asemhaling en lae bloeddruk veroorsaak.
- Witbloedsel (leukosiettransfusies). Skielike en ernstige probleme in die longe kan voorkom wanneer **TERISOM** aan jou toegedien word tydens of kort na

witbloedseltransfusie. Jou dokter sal aanbeveel dat die infusies vir so lang periode as moontlik van mekaar toegedien word. Dit sal die risiko van longprobleme verlaag en jou longe sal gemonitor word.

TERISOM *saam met voedsel, drinkgoed en alkohol:*

Geen interaksie is aangemeld met voedsel, drinkgoed en alkohol nie.

Swangerskap, borsvoeding en fertiliteit

Swangerskap

As jy swanger is of borsvoed, dink dat jy swanger mag wees, of beplan om ‘n baba te hê, vra asseblief jou dokter of apteker vir advies voordat jy hierdie medisyne ontvang.

Die veiligheid van **TERISOM** tydens swangerskap is nie bekend nie.

Borsvoeding

Lig jou dokter in as jy borsvoed. Jy moenie borsvoed tydens behandeling met **TERISOM** nie**.**

Bestuur en gebruik van masjinerie:

Moenie bestuur of masjinerie hanteer nie.

Sommige van die moontlike newe-effekte van **TERISOM** kan jou vermoë om te bestuur of masjinerie veilig te gebruik, affekteer, Sien Afdeling 4, Moontlike newe-effekte.

TERISOM bevat sukrose

As jy deur jou dokter ingelig is dat jy ‘n onverdraagsaamheid teen sommige suikers het, moet jy jou dokter kontak voordat voordat **TERISOM** toegedien word.

3. Hoe om TERISOM te gebruik:

TERISOM sal altyd deur jou dokter of verpleegkundige aan jou toegedien word. Die dosis van **TERISOM** hang af van liggaamsgewig en word aangepas om aan die behoeftes van elke individuele pasiënt te voorsien. Jou dokter sal op ‘n toepaslike dosis vir jou besluit.

Vermoedelike fungusinfeksies:

Die aanbevole daaglikse dosis is 3 mg per kg liggaamsgewig, per dag.

Fungusinfeksies van een of meer diep organe van die liggaam:

Die aanbevole daaglikse dosis is 3-5 mg per kg liggaamsgewig, per dag. Die duur van terapie sal op 'n individuele basis deur jou dokter bepaal word.

Fungusinfeksie van die weefsels wat die brein en spinaalkoord bedek (Kriptokokkale meningitis)

Die aanbevole daaglikse dosis is 6 mg per dag.

Visserale leishmaniase:

Die aanbevole daaglikse dosis is 3 - 4 mg/dag.

Jou doker sal besluit oor die hoeveelheid van **TERISOM** wat jy sal ontvang en oor hoeveel dae dit toegedien sal word.

Kinders

TERISOM is gebruik om kinders van die ouderdom van 1-maand tot 18-jaar oud, te behandel. **TERISOM** is nie in babas onder die ouderdom van 1-maand oud bestudeer nie.

Bejaardes

Geen verandering in dosis of frekwensie van infusie word vir bejaarde pasiënte benodig nie.

Pasiënte met verlaagde nierfunksie:

Geen verandering in dosis of frekwensie van infusie word benodig nie. Jou dokter sal gereëlde bloedmonsters neem om te toets vir veranderinge in nierfunksie.

As jy onder die indruk is dat die effek van **TERISOM** te sterk of te swak is, moet jy met jou dokter of apteker praat. Die dosis sal op gereëlde tussenposes deur jou dokter

gekontrolleer word, indien nodig. Vra jou dokter of apteker as jy enige verdere vrae het oor die gebruik van hierdie medisyne.

Metode van toediening:

Om die infusie te berei, moet **TERISOM** opgelos word in steriele water vir inspuiting en dan verdun word met ‘n oplossing wat dekstrose bevat.

TERISOM moet nie met soutoplossings of met ander medisinale produkte of elektroliete gemeng word nie.

As jy ‘n hoër dosis van **TERISOM** ontvang as wat jy behoort te ontvang:

Aangesien ‘n gesondheidsorgvoorsiener **TERISOM** sal toedien, sal hy / sy die dosis kontrolleer. In die geval van oordosering, sal jou dokter egter die oordosis beheer.

As jy vergeet om **TERISOM** te gebruik:

Aangesien ‘n gesondheidsorgvoorsiener **TERISOM** sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

Vra jou dokter, apteker of verpleegkundige as jy enige verdere vrae het.

4. Moontlike newe-effekte

TERISOM kan newe-effekte hê.

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

As jy opmerk dat enige van die volgende gebeur, moet jy jou dokter onmiddellik inlig:

- ‘n Ernstige, potensieel lewensbedreigende allergiese reaksie (anafilaktiese reaksies)

- ‘n Pienk of rooi uitslag met of sonder etter-gevulde bulte of blase, skubberige, skilferige vel, koors, swelling van die gesig, geswelde of teer limfknope, geswelde speekselkliere, droë mond (Hipersensitiwiteitsreaksie)

Hierdie is almal baie ernstige newe-effekte. As jy hulle het, kon jy ‘n ernstige reaksie teen **TERISOM** gehad het. Jy mag dringende mediese aandag benodig.

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

- Moeilike asemhaling, hyging of hoes (brongospasma)
- ‘n Toestand waarin daar ‘n afname is in die aantal rooibloedselle (anemie)
- Hartaanval (hartverlamming)
- Pynlose swelling onder die vel (angioneurotiese edeem)

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

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

Dikwelse newe-effekte:

- Lae kaliumvlakke in die bloed (hipokalemie)
- Lae magnesiumvlakke in die bloed (hipomagnesemie)
- Lae kalsiumvlakke in die bloed (hipokalsemie)
- Hoë suiker- (glukose) vlakke in die bloed (hiperglukemie)
- Lae natriumvlakke in die bloed (hiponatremie)
- Hoofpyn
- Vinnige hartklop (tagikardie)
- Verwyding van bloedvate (vasodilatasie)
- Blosing
- Lae bloeddruk (hipotensie)
- Naarheid
- Braking

- Diaree
- Abdominale pyn
- Jou lewer is ontsteek (lewerfunksie toetse abnormaal)
- Abnormale hoë vlakke van bilirubien (hiperbilirubinemie)
- Verhoogde lewerensieme (alkaliese fosfatase verhoog)
- Verhoogde kreatinien
- Bloedureum verhoog
- Uitslag
- Rugpyn
- Koors of hoë temperatuur (pireksie)
- ‘n Skielike gevoel van koue of bewerigheid gepaardgaande met ‘n verhoging in temperatuur (koudheid)
- Borskaspyn

Minder dikwelse newe-effekte:

- Lae bloedplaatjie-telling (trombositopenie)
- Konvulsie
- Veranderinge in die manier waarop die hart klop (arritmie)
- Niersiekte waar jy min of geen urine passeer (nierversaking)
- Swak nierfunksie (nierontoereikendheid)
- “n Afbraak van spierweefsel wat ‘n beskadigende proteïen in die bloed vrystel (rabdomiolise)
- Gewrigspyn (artralgie)

Newe-effekte gedurende die infusie

Dikwelse newe-effekte: koors, koudheid, en bewerigheid.

Minder dikwelse infusie-verwante newe-effekte sluit in: benoude bors, borskaspyn, asemloosheid, moeilike asemhaling (moontlik met hyging), blosing, 'n vinniger hartritme as normaal, lae bloeddruk en muskuloskeletale pyn (beskyf as gewrigspyn, rugpyn, of beenpyn).

Hierdie newe-effekte klaar vinnig op wanneer die infusie gestaak word. Hierdie reaksies mag nie met toekomstige infusies van **TERISOM** voorkom nie of met 'n stadiger infusie (oor 2 uur). Jou dokter mag ander medisyne aan jou toedien om infusie-verwante reaksies te voorkom, of om die simptome te behandel as jy dit kry. As jy 'n ernstige infusie-verwante reaksie kry, sal jou dokter die **TERISOM-**infusie staak en jy moenie hierdie behandeling in die toekoms ontvang nie. As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk aangemeld word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn beskikbaar is onder SAHPRA se publikasies:

https://www.sahpra.org.za/Publications/Index/8

Deur newe-effekte aan te meld, kan jy help om meer inligting te verskaf oor die veiligheid van **TERISOM**.

5. Hoe om TERISOM te bewaar

Onoopgemaakte TERISOM flessies:

Bewaar alle medisyne buite die bereik van kinders.

Bewaar by of onder 25 °C.

Moenie hierdie medisyne na die vervaldatum soos op die karton aangedui, gebruik nie.

6. Inhoud van die verpakking en ander inligting

Wat TERISOM bevat

Di-stearoïelfosfatidiel gliserol, Gehidrogeneerde soja fosfatidielcholien, Cholesterol NF, DL-Alfa-Tokoferol USP, Sukrose NF, Natriumsuksinaat dibasiese heksahidraat.

Hoe TERISOM lyk en inhoud van die verpakking

Geel gevriesdroogde koekie of poeier, vry van sigbare bewys van kontaminasie.

Hersaamgestelde oplossing: Geelkleurige suspensie vry van sigbare vreemde deeltjies.

TERISOM word aangebied in 15 mL, 20 mL of 30 mL steriele, Tipe-I glasflessies. Die prop bestaan uit ‘n grys butielrubberprop en aluminiumringseël toegerus met ‘n plastiekdoppie wat verwyder kan word. Tien enkeldosis flessies word per karton verpak saam met 10 filters. Nie alle pakgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14, Stomill, Uitbreiding 1

Roodepoort, 1724

Hierdie inligtingstuk was laaste hersien in

20 Junie 2023

Registrasienommers

56/20.2.2/1125