PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PEXITAZ 100 Powder for solution for infusion
PEXITAZ 500 Powder for solution for infusion
(Pemetrexed)
(Contains mannitol)

Read all of this leaflet carefully before you are given PEXITAZ.

- 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

- What PEXITAZ is and what it is used for
- What you need to know before you use PEXITAZ
- How to use PEXITAZ
- Possible side effects
- How to store PEXITAZ
- Contents of the pack and other information

1. What PEXITAZ is and what it is used for

PEXITAZ is a medicine used in the treatment of cancer.
PEXITAZ is given in combination with cisplatin, another anti-cancer medicine, as treatment for malignant pleural mesothelioma, a form of cancer that affects the lining of the lung.
PEXITAZ is also given in combination with cisplatin for the initial treatment of patients with advanced stage of lung cancer.
PEXITAZ can be prescribed to you if you have lung cancer at an advanced stage if your disease has responded to treatment or it remains largely unchanged after initial chemotherapy.
PEXITAZ is also a treatment for patients with advanced stage of lung cancer whose disease has progressed after other initial chemotherapy has been used.

2. What you need to know before you use PEXITAZ

Do not use PEXITAZ:

- if you are hypersensitive (allergic) to pemetrexed or any of the other ingredients of PEXITAZ (listed in section 6).
- if you are pregnant or breastfeeding your baby.
- if you have recently received or are about to receive a vaccine against yellow fever.

Warnings and precautions

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

- If you currently have or have previously had problems with your kidneys, talk to your doctor or hospital pharmacist as you may not be able to receive PEXITAZ.
- Before each infusion you will have samples of your blood taken to evaluate if you have sufficient kidney and liver function and to check that you have enough blood cells to receive PEXITAZ. Your doctor may decide to change the dose or delay treating you depending on your general condition and if your blood cell counts are too low. If you are also receiving cisplatin, your doctor will make sure that you are properly hydrated and receive appropriate treatment before and after receiving cisplatin to prevent

vomiting.

- If you have had or are going to have radiation therapy, please tell your doctor, as there may be an early or late radiation reaction with PEXITAZ.
- If you have been recently vaccinated, please tell your doctor, as this can possibly cause bad effects with PEXITAZ.
- If you have heart disease or a history of heart disease, please tell your doctor.
- If you have an accumulation of fluid around your lungs, your doctor may decide to remove the fluid before giving you PEXITAZ.
- If you are taking any medicine for pain or inflammation (swelling), called “nonsteroidal anti-inflammatory drugs” (NSAIDs), including medicines purchased without a doctor’s prescription (such as ibuprofen). There are many sorts of NSAIDs with different durations of activity. Based on the planned date of your infusion of pemetrexed and/or on the status of your kidney function, your doctor needs to advise you on which medicines you can take and when you can take them. If you are unsure, ask your doctor or pharmacist if any of your medicines are NSAIDs.
- If you experience skin reactions during your anticancer treatment, your doctor may then prescribe corticosteroids to reduce the frequency and severity of the skin reactions.

If any of the above applies to you (or you are not sure), consult your doctor, pharmacist or healthcare professional before you are given PEXITAZ.

Children and adolescents
There is no relevant use of pemetrexed in the paediatric population.

Other medicines and PEXITAZ
Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).
Certain nephrotoxic medicine (medicine causing injury to the kidneys such as aminoglycosides (antibiotic), loop-diuretics (water tablets), platinum compounds (medicine used to treat cancer), ciclosporin medicine used in organ or bone marrow transplantation) may interact with PEXITAZ and cause a delay in the excretion of PEXITAZ from the body.
Concomitant administration of probenecid (medicine used for treatment of gout), could potentially cause a delay in the excretion of PEXITAZ from the body.

Higher doses of anti-inflammatory medicines (taken for pain and inflammation) may decrease the elimination of PEXITAZ from the body. Depending on the advice of your physician, treatment with these medicines may need to be interrupted 2 to 5 days before administration of PEXITAZ.

Possible interaction between anticoagulants (blood thinning (medicines) and PEXITAZ may require more frequent blood tests and monitoring.

If you have been recently vaccinated, please tell your doctor, as this can possibly cause bad effects with PEXITAZ.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving PEXITAZ

PEXITAZ with food and drink
There are no known interactions between PEXITAZ and food or drink. Refer to Section 4.5 of the PI (Interaction with other medicines and other forms of interaction).

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

Pregnancy
The use of PEXITAZ should be avoided during pregnancy due to possible harm to the baby. Your doctor will discuss with you the potential risk of taking PEXITAZ during pregnancy. Women are therefore advised not to become pregnant while being treated with PEXITAZ .Women must use effective contraception during treatment with PEXITAZ.

Breastfeeding
You should not breastfeed your baby during PEXITAZ treatment.

Fertility
Men are advised not to father a child during and up to 6 months following treatment with PEXITAZ and should therefore use effective contraception during treatment with PEXITAZ and for up to 6 months afterwards. If you would like to father a child during the treatment or in the 6 months following receipt of treatment, seek advice from your doctor or pharmacist. You may want to seek counselling on sperm storage before starting your therapy.

Driving and using machines
PEXITAZ may make you feel tired. You should not drive a car or use machines until you know how PEXITAZ will affect you.

PEXITAZ contains sodium
PEXITAZ 100 contains 11 mg (< 1 mmol) sodium per vial, i.e. it is essentially “sodium-free”.
PEXITAZ 500 contains approximately 54 mg (2,35 mmol) sodium per vial. You should take into consideration if you are on a controlled sodium diet.

3. How to use PEXITAZ
Do not share medicines prescribed for you with any other person.
You will not be expected to give yourself PEXITAZ. It will be given to you by a person who is qualified to do so.

The usual dose of PEXITAZ is 500 milligrams for every square metre of your body’s surface area. Your height and weight are measured to work out the surface area of your body. Your doctor will use this body surface area to work out the right dose for you. This dose may be adjusted, or treatment may be delayed depending on your blood cell counts and on your general condition. A hospital pharmacist, nurse or doctor will have mixed the PEXITAZ powder with 9 mg/ml (0,9 %) sodium chloride solution for injection before it is given to you.
You will always receive PEXITAZ by infusion into one of your veins. The infusion will last approximately 10 minutes.
You should usually receive your infusion once every 3 weeks.
When using PEXITAZ in combination with cisplatin:
The doctor or hospital pharmacist will work out the dose you need based on your height and weight. Cisplatin is also given by infusion into one of your veins, and is given approximately 30 minutes after the infusion of PEXITAZ has finished. The infusion of cisplatin will last approximately 2 hours.

Additional medicines:
Corticosteriods: your doctor will prescribe you steroid tablets (equivalent to 4 milligram of

dexamethasone twice a day) that you will need to take on the day before, on the day of, and the day after PEXITAZ treatment. This medicine is given to you to reduce the frequency and severity of skin reactions that you may experience during your anticancer treatment.

Vitamin supplementation: your doctor will prescribe you oral folic acid (vitamin) or a multivitamin containing folic acid (350 to 1000 micrograms) that you must take once a day while you are taking PEXITAZ. You must take at least 5 doses during the seven days before the first dose of PEXITAZ. You must continue taking the folic acid for 21 days after the last dose of PEXITAZ. You will also receive an injection of vitamin B_{12} (1000 micrograms) in the week before administration of PEXITAZ and then approximately every 9 weeks (corresponding to 3 courses of PEXITAZ treatment). Vitamin B_{12} and folic acid are given to you to reduce the possible toxic effects of the anticancer treatment.

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

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

If you are given more PEXITAZ than you should
Since a health care provider will administer PEXITAZ, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you experience any side effects after being given PEXITAZ, immediately tell your doctor or nurse or go to the Emergency Department at your nearest hospital. You may need urgent medical attention.

If you missed a dose of PEXITAZ
Since a health care provider will administer PEXITAZ, it is unlikely that the dose will be missed.

4. Possible side effects
PEXITAZ can have side effects.
Not all side effects reported for PEXITAZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PEXITAZ, please consult your healthcare provider for advice.

If any of the following happens while you are being treated with PEXITAZ, tell your doctor immediately or go to the casualty department of your nearest hospital:

- severe allergic reaction (anaphylactic shock); signs and symptoms include:
  - skin reactions, including hives and itching and flushed or pale skin.
  - low blood pressure (hypotension).
  - constriction of your airways and a swollen tongue or throat, which can cause wheezing and trouble breathing.
  - a weak and rapid pulse.
  - nausea, vomiting or diarrhea.
  - dizziness or fainting
- skin rash/hives, itching, burning or prickling sensation, fever, swelling of hands, feet, ankles, face, lips and mouth or throat which may cause difficulty in swallowing or breathing (allergic reaction),
- skin reactions may be severe and could lead to death. Contact your doctor if you get a severe rash, or itching, or blistering (Stevens - Johnson syndrome or Toxic epidermal necrolysis),

- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) [erythema multiforme].

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

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

Frequent side effects:

- fever or infection: if you have a temperature of 38 °C or greater, sweating or other signs of infection (since you might have less white blood cells than normal). Infection (sepsis) may be severe and could lead to death,
- pain, redness, swelling or sores in your mouth,
- tiredness, feeling faint, becoming easily breathless or if you look pale (since you might have less haemoglobin than normal),
- bleeding from the gums, nose or mouth or any bleeding that would not stop, reddish or pinkish urine, unexpected bruising (since you might have less platelets than normal).

Less frequent side effects:

- chest pain or having a fast heart rate,
- sudden breathlessness, intense chest pain or cough with bloody sputum (may indicate a blood clot in the blood vessels of the lungs),
- inflammation of the liver characterised by yellow pigmentation to the skin, mucus membrane or eyes, pale coloured stools, dark coloured urine, skin itch, rash, pain (hepatitis),
- inflammation of the lining of the large bowel, which may be accompanied by intestinal or rectal bleeding,
- scarring of the air sacs of the lung (interstitial pneumonitis),
- some patients have experienced a heart attack, stroke or “mini-stroke” while receiving PEXITAZ usually in combination with another anticancer therapy,
- inflammation of the lining of the oesophagus (gullet) has been experienced with pemetrexed/ radiation therapy.

Frequency unknown:

- passing much more or much less urine than usual, which may be a symptom of a type of kidney problem (renal tubular necrosis).

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:

- loose stools (diarrhoea),
- feeling or being sick,
- indigestion,
- loss of appetite,
- tiredness,
- skin rash,
- hair loss,
- constipation,
- loss of sensation,
- kidney: abnormal blood tests,
- fever,

- dehydration,
- kidney failure,
- irritation of the skin and itching,
- inflamed eye (conjunctivitis),
- taste change,
- liver: increased alanine and aspartate aminotransferase (blood test),
- excess fluid in body tissue, causing swelling (oedema),
- pain,
- increased skin pigmentation,
- muscle weakness,
- pain in the abdomen.

Less frequent side effects:
- watery eyes,
- pancytopenia- combined low counts of white cells, red cells and platelets,
- irregular heartbeat,
- increased gamma-glutamyl transferase,
- hives.

Frequency unknown:
- scarring of the air sacs of the lung associated with radiation therapy (radiation pneumonitis) may occur in patients who are also treated with radiation either before, during or after their pemetrexed therapy,
- extremity pain, low temperature and discolouration have been reported,
- skin rash like severe sunburn (radiation recall) which can occur on skin that has previously been exposed to radiotherapy, from days to years after the radiation,
- antibody-mediated destruction of red blood cells (immune mediated haemolytic anaemia),
- lower limb swelling with pain and redness,
- thirst and increased water consumption,
- increased sodium in blood,
- inflammation of the skin, mainly of the lower limb with swelling, pain and redness.

You might have any of these symptoms and/or conditions. You must tell your doctor as soon as possible when you start experiencing any of these side effects.

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 PEXITAZ.

5. How to store PEXITAZ
Store all medicines out of reach of children.
Store at or below 25 °C (room temperature).
Do not use after the expiry date stated on the label and carton.
After reconstitution, PEXITAZ should be used immediately. When prepared as directed,

chemical and physical in-use stability of reconstituted and infusion solutions of PEXITAZ were demonstrated for 24 hours at refrigerated temperature.

6. Contents of the pack and other information

What PEXITAZ contains

- The active ingredient is pemetrexed.
- The other ingredients are hydrochloric acid, mannitol (sugar), nitrogen pure, sodium hydroxide

PEXITAZ 100
Each vial contains 100 mg of pemetrexed (as pemetrexed disodium heptahydrate).
Contains sugar: mannitol.

PEXITAZ 500
Each vial contains 500 mg of pemetrexed (as pemetrexed disodium heptahydrate).
The reconstituted **PEXITAZ** solution contains 25 mg/ml pemetrexed.
Contains sugar: mannitol.

What PEXITAZ looks like and contents of the pack

PEXITAZ 100:
Powder for solution for infusion.
White to either light yellow or green yellow lyophilized powder.
Each carton contains a 10 ml colourless tubular vial with grey rubber stopper and sealed with light green F/O both sides clear lacquer coated seal.
PEXITAZ 500:
Powder for solution for infusion.
White to either light yellow or green yellow lyophilized powder.
Each carton contains a 50 ml colourless moulded vial with grey rubber stopper and sealed with light green F/O both sides clear lacquer coated seal.

Holder of Certificate of Registration

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PATIENT INFORMATION LEAFLET

SKEDULERINGSTATUS: S4

PEXITAZ 100 Poeier vir oplossing vir infusie
PEXITAZ 500 Poeier vir oplossing vir infusie
(Pemetreksed)
(Bevat mannitol)

Lees hierdie hele pampflet versigtig deur voordat u PEXITAZ ontvang.
- Hou hierdie pamflet. Dit mag nodig wees dat u dit weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, verpleegster, of ander gesondheidsorgverskaffer.

Wat is in hierdie pamflet

- Wat PEXITAZ is en waarvoor dit gebruik word
- Wat u moet weet voordat u PEXITAZ gebruik
- Hoe om PEXITAZ te gebruik
- Moontlike newe-effekte
- Hoe om PEXITAZ te berg
- Inhoud van die pak en ander inligting

1. Wat PEXITAZ is en waarvoor dit gebruik word
PEXITAZ is ‘n medisyne wat vir die behandeling van kanker gebruik word.
PEXITAZ word gegee in kombinasie met sisplatien, ‘n ander antikankermedisyne, as behandeling van kwaadaardige pleurale mesothelioom, ‘n vorm van kanker wat die voering van die long affekteer.
Dit word ook in kombinasie met sisplatien gegee vir die aanvanklike behandeling van pasiënte met gevorderde stadium van longkanker.
PEXITAZ kan aan u voorgeskryf word as u longkanker grootliks onveranderd bly na aanvanklike chemoterapie.
PEXITAZ is ook ‘n behandeling vir pasiënte met gevorderde stadium van longkanker, wie se siekte gevorder het na aanvanlik ander chemoterapie gebruik is.

2. Wat u moet weet voordat u PEXITAZ gebruik
Moet nie PEXITAZ gebruik nie indien:
- U hipersensitief (allergies) is vir pemetreksed of enige van die ander bestanddele van PEXITAZ nie (gelys in seksie 6).
- U swanger is of u baba borsvoed.
- U onlangs ‘n vaksien (entstof) teen geelkoors ontvang het, of beplan om dit te ontvang,

Waarskuwings en voorsorgmaatreëls
Vertel u dokter of gesondheidsorgverskaffer voordat u die inspuiting ontvang:
- Indien u nou of voorheen probleme met u niere gehad het, praat met u dokter of hospitaalapteker, omdat jy moontlik nie PEXITAZ sal kan ontvang nie.
- Voor elke infusie sal monsters van jou bloed geneem word om vas te stel of jy genoegsame nier- en lewerfunksie het en te verseker dat jy genoeg bloedselle het om PEXITAZ te ontvang. U dokter mag besluit om jou dosis te verander of om jou behandeling uit te stel afhangende van jou algemene toestand en as jou bloedseltellings te laag is. Indien u ook sisplatien ontvang, sal u dokter verseker dat u behoorlik gehidreer is en die toepaslike behandeling ontvang voor en nadat jy sisplatien ontvang het om braking te voorkom.
- Indien u radiasieterapie ontvang het of gaan ontvang, vertel u dokter, want daar mag ‘n vroeër of latere radiasiereaksie met PEXITAZ wees.
- Indien u onlangs ingeënt is, vertel asseblief u dokter, want dit kan moontlik slegte effekte met PEXITAZ veroorsaak.
- Indien u ‘n hartsiekte het of ‘n geskiedenis het van hartsiekte, vertel asseblief u dokter.

- Indien u ‘n opeenhoping van vloeistof om die longe het, mag jou dokter besluit om die vloeistof te verwyder voordat hy PEXITAZ aan jou gee.
- Indien u enige medisyne neem vir pyn of inflammasie (swelling), genoem nie-steroïedale anti-inflammatoriese middels (NSAIMs, insluitende medisyne wat gekoop word sonder ‘n doktersvoorskrif (soos ibuprofeen). Daar is baie soorte met verskillende duur van werking. Gebasseer op die beplande datum vir jou pemetreksed-infusie en/of op die status van jou nierfunksie, moet jou dokter jou adviseer aangaande watter medisyne jy kan neem en wanneer jy dit kan neem. Indien jy onseker is, vra jou dokter of apteker of enige van jou medisyne NSAIMs is.
- Indien jy velreaksies ondervind gedurende jou antikanker behandeling, mag jou dokter dan kortikosteroïede voorskryf om die frekwensie an ernstigheid van die velreaksies te verminder.

Indien enige van die bostaande op jou van toepassing is, praat met jou dokter, apteker of gesondheidsorgwerker voordat jy PEXITAZ ontvang.

Kinders en adolessente
Daar is geen relevante gebuik van pemetreksed in die pediadriese polulasie nie.

Ander medisyne met PEXITAZ
Vertel altyd jou gesonheidsorgverskaffer indien jy enige ander medisyne neem (dit sluit alle komplementêre en tradisionele medisyne in).
Sekere nefrotoksiese medisyne (medisyne wat besering veroorsaak aan die niere, soos aminoglikosiede (antibiotika), lus diuretika (water tablette), platiniumverbindings (medisyne om kanker te behandel), siklosporien (medisyne gebruik in orgaan- of beenmurgoorplanting) mag interaksies hê met PEXITAZ en kan ‘n vertraging veroorsaak in die uitskeiding van PEXITAZ uit die liggaam.
Gelyktydige toediening van probenesied (medisye gebruik in die behandeling van jig), kan moontlik ‘n vertraging in die uitskeiding van PEXITAZ uit die liggaam veroorsaak.

Hoër dosisse anti-inflammatoriese medisyne (geneem vir pyn en inflammasie) kan ‘n vertraging in die uitskeiding van PEXITAZ uit die liggaam veroorsaak. Afhangende van die advies van jou dokter, mag dit nodig wees om die behandeling met hierdie medisyne te onderbreek vir 2 tot 5 dae voor toediening van PEXITAZ.
Moontlike interaksie tussen antikoagulante (bloedverdunner medisyne) en PEXITAZ mag meer dikwelse bloedtoetse en monitering benodig.

Indien u onlangs ingeënt is, vertel asseblief jou dokter, want dit kan moontlik slegte effekte met PEXITAZ veroorsaak.

U dokter en apteker het meer inligting oor medisyne om versigtig mee te wees of te vermy terwyl PEXITAZ ontvang word.

PEXITAZ met voedsel en drank
Daar is geen bekende interaksies tussen PEXITAZ met voedsel of drank nie. Verwys na seksie 4.5 van die PI (Interaksie met ander medisyne en ander vorms van interaksie).

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of jou baba borsvoed, dink dat u swanger mag wees of beplan om ‘n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat PEXITAZ gebruik word.

Swangerskap
Die gebruik van PEXITAZ moet vermy word gedurende swangerskap as gevolg van moontlike skade aan die baba. U dokter sal die moontlike risiko van PEXITAZ se gebruik tydens swangerskap met u bespreek. Vrouens word dus aanbeveel om nie swanger te raak tydens behandeling met PEXITAZ nie. Vrouens moet effektiewe kontrasepsie gebruik tydens behandeling met PEXITAZ.

Borsvoeding
U moet nie jou baba borsvoed tydens PEXITAZ-behabdeling nie.

Fertiliteit
Mans word aanbeveel om nie ‘n kind te verwek gedurende en tot 6 maande na behandeling met PEXITAZ nie en moet dus gedurende PEXITAZ-behandeling en tot 6 maande daarna effektie kontrasepsie gebruik. Indien u ‘n kind wil verwek gedurende behandeling of gedurende die 6 maande wat volg na die behandeling ontvang is, raapleeg jou dokter of apteker vir advies. U mag berading wil soek aangaande die stoor van sperm voordat jou behandeling begin word.

Bestuur en gebruik van masjiene
PEXITAZ kan jou moeg laat voel. U moet nie ‘n motor bestuur of masjiene gebruik totdat u weet hoe PEXITAZ jou sal affekteer nie.

PEXITAZ bevat natrium
PEXITAZ 100 bevat 11 mg (< 1 mmol) natrium per flessie, dus in wese“vry van natium”.
PEXITAZ 500 bevat ongeveer 54 mg (2,35 mmol) natrium per flessie. U moet dit in ag neem indien u op ‘n natrium-gekontroleerde dieet is.

3. Hoe om PEXITAZ te gebruik
Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Daar sal nie van u verwag word om PEXITAZ aan uself toe te dien nie. Dit sal aan u toegedien word deur iemand wat gekwalifiseerd is om dit te doen.

Die normale dosis PEXITAZ is 500 milligram vir elke vierkante meter van jou liggaamsoppervlakte. U lengte en gewig word gemeet om jou liggaamsoppervlakte te bepaal. U dokter sal hierdie liggaamsoppervlakte gebruik om die regte dosis vir jou uit te werk. Hierdie dosis mag aangepas word of die behandeling uitgestel word, afhangende van jou bloedseltellings en van jou algemene toestand. ‘n Hospitaalapteker, verpleegster of dokter sou die PEXITAZ-poeier gemeng het met 9 mg/ml (0,9 %) natriumchloried oplossing vir inspuiting voordat dit aan u toegedien word.
U sal altyd PEXITAZ deur infusie in een van jou are ontvang. Die infusie sal ongeveer 10 minute duur.
U behoort gewoonlik jou infusie eenmaal elke 3 weke te ontvang.
Indien PEXITAZ in kombinasie met sisplatien gebruik word:
Die doter of hospitaalapteker sal die dosis wat jy nodig het, gebasseer op jou lengte en gewig uitwerk. Sisplatien word ook deur infusie in een van jou are toegedien en word gegee ongeveer 30 minute na die infusie met PEXITAZ voltooi is. Die infusie met sisplatien sal ongeveer 2 ure duur.

Addisionele medisyne
Kortikosteroïde: U dokter sal steroïedtablette (ekwivalent aan 4 milligram deksametasoon tweekeer per dag) aan u voorskryf wat u neem op die dag voor, op die dag van en die dag na PEXTAZ-behandeling. Hierdie medisyne word gegee om die frekwensie en ernstigheid van velreaksies te vermider wat u tydens jou antikankerbehandeling mag ervaar.

Vitamien-supplementasie: U dokter sal aan u orale foliensuur (vitamien) of ‘n multivitamien wat foliensuur (350 to 1000 microgram) bevat, voorskryf wat u eenmaal per dag moet neem terwyl u PEXITAZ gebruik. U moet ten minste 5 dosisse gedurende die sewe dae voor die eerste dosis PEXITAZ neem. U moet aanhou om die foliensuur te neem vir 21 dae na die laaste PEXITAZ-dosis. U sal ook ‘n vitamien B_{12} (1000 mikrogram) inspuiting in die week voor toediening van PEXITAZ ontvang en dan ongeveer elke 9 weke (in ooreenstemming met 3 kursusse PEXITAZ-behandeling). Vitamien B_{12} en foliensuur word gegee om die moontlike toksiese effekte van antikanker-behandeling te verlaag.

U dokter sal vir u sê vir hoe lank u behandeling sal voortduur. Indien u die indruk kry dat die effek van PEXITAZ te sterk of te swak is, raadpleeg u dokter of apteker.

Indien u enige verdere vra het oor die gebruik van hierdie medisyne, vra u dokter of apteker.

Indien u meer PEXITAZ toegedien is as wat moes

Aangesien ‘n gesonheidsorgverskaffer PEXITAZ sal toedien, sal hy/sy die dosis beheer. In geval van ‘n oordosis sal u dokter die oordosering hanteer.

Indien u enige newe-effekte na die toediening van PEXITAZ ondervind, vertel dit onmiddellik aan jou dokter of verpleegster of gaan na die ongevalle afdeling by jou naaste hospitaal. U mag dringende mediese aandag benodig.

Indien u ‘n dosis PEXITAZ oorgeslaan het
Aangesien ‘n gesonheidsorgverskaffer PEXITAZ sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte

PEXITAZ kan newe-effekte hê.
Nie alle newe-effekte wat vir PEXITAZ aangemeld is, word in hierdie pamflet aangedui nie. Indien u algemene gesonheid verswak of indien u enige ongewenste newe-effekte ervaar terwyl u PEXITAZ gebruik, raadpleeg asseblief u gesondheidsorgverkaffer vir advies.

Indien enige van die volgende gebeur terwyl u met PEXITAZ behandel word, vertel dadelik vir u dokter daarvan of gaan na die ongevalle afdeling by u naaste hospitaal:

- ernstige allergiese reaksie (anafilaktiese skok); tekens en simptome sluit in:
  - velreaksies, ingeslote bulte en jeukerigheid en gloeiende of bleek vel.
  - lae bloeddruk (hipotensie).
  - vernouing van jou lugweë en swelling van tong of keel, wat fluiting en moeilike asemhaling kan veroorsaak.
  - ‘n swak en vinnige pols.
  - naarheid, braking of diarree.
  - lighoofdigheid of floute.
- veluitslag/bulte, jeukerigheid, brand- of prikkelende sensasie, koors, swelling van hande, voete, enkels, gesig, lippe en mond of keel, wat sluk of asemhaling kan bemoeilik (allergiese reaksie),
- velreaksies kan ernstig wees en tot dood lei. Kontak jou dokter indien jy ‘n ernstige uitslag of jeukerigheid of blase (Stevens – Johnson-sindroom of Toksiese epidermale nekrolise), kry,
- veluitslag, wat blase kan vorm en soos klein teikens lyk (donker kolle in die middel omring met ‘n ligter area, met ‘n donker ring om die kante) [erithema multiforme].

Hierdie is almal baie ernstige newe-effekte. Indien u hulle het kon u ’n ernstige reaksie teenoor PEXITAZ gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel dadelik vir u dokter of gaan na die ongevalle afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
Algemene newe-effekte:

- koors of infeksie: indien u ‘n koors van 38 °C of hoër het, sweet of ander tekens van infeksie (aangesien jy minder witbloedselle as normaal mag hê). Infeksie (sepsis) mag ernstig wees en tot dood lei,
- pyn, rooiheid, swelling of sere in jou mond,
- moegheid, flou voel, maklik uitasem word of bleek lyk (aangesien jy minder hemoglobien kan hê as normaalweg,
- bloeding van tandvleis, neus of mond of enige bloeding wat nie wil stop nie, rooierige tot rooskleurige urine, onverwagte kneusing (aangesien jy minder plaatjies kan hê as normaalweg).

Minder algemene newe-effekte:

- borspyn of ‘n vinnige harttempo,
- skielik uitasem wees, intense borspyn of hoes met bloederige sputum (mag dui op ‘n bloedklont in die bloedvate van die longe),
- inflammasie van die lewer, soos aangedui deur geel pigmentasie van die vel, mukusmembrane van die oë, bleekkleurige stoelgange, donkerkleurige urine, jeukerige vel, uitslag, pyn (hepatitis),

- inflammasie van die voering van die grootderm, wat gepaard kan gaan met intestinale of rektale bloeding,
- littekens van die lugsakke van die long (interstisiële pneumonitis),
- sommige pasiënte het ‘n hartaanval, beroerte of mini-beroete ervaar terwyl hul PEXITAZ ontvang het, gewoonlik in kombinasie met ‘n ander antikankerterapie,
- inflammasie van die voering van die esofagus (slukderm) is ervaar met pemetreksed/radiasie-terapie.

Frekwensie onbekend:
- passeer baie meer of baie minder urine as gewoonlik, wat ‘n simptoom van ‘n nierprobleem (renale tubulêre nekrose) kan wees.

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

Vertel u dokter indien u enige van die volgende opmerk:
Algemene newe-effekte:
- los stoelgange (diarree),
- siek te voel of siek te wees,
- slegte spysvertering,
- verlies aan eetlus,
- moegheid.
- veluitslag,
- haarverlies,
- hardlywigheid,
- verlies van sensasie,
- nier: abmormale bloedtoets,
- koors,
- dehidrasie,
- nierversaking,
- irritasie van die vel en jeukerigheid,
- ooginfeksie (konjunktivitis),
- smaakveranderinge,
- lewer: verhoogde alanien en aspartaat-aminotransferase (bloedtoets),
- oormatige vloeistof in liggaamsweefsel wat swelling veroorsaak (edeem),
- pyn,
- verhoogde velpigmentasie,
- spierswakheid,
- pyn in die abdomen.

Minder algemene newe-effekte:
- waterige oë,
- pansitopenie- gekombineerde lae tellings van wit selle, rooi selle en plaatjies,
- onreëlmatige hartklop,
- verhoogde gamma-glutamiel transferase,
- bulte

Frekwensie onbekend:
- littekens van die lugsakke van die long met radiasieterapie (radiasie pneumonitis) mag voorkom by pasiënte wat ook met radiasie behandel is voor, gedurende of na hul pemetreksed-behandeling,
- pyn van ledemate, lae temperatuur en verkleuring is aangemeld,
- veluitslag, soos erge sonbrand (herroeping van radiasie) wat kan voorkom op vel wat voorheen aan radioterapie blootgestel is, vanaf dae tot jare na radiasie,
- teenliggaambemiddelde vernietiging van rooibloedselle (immuunbemiddelde hemolitiese anemie),
- swelling van laer ledemate met pyn en rooiheid,
- dorstigheid en verhoogde waterinname,
- verhoogde natrium in bloed,

- inflammasie van die vel, hoofsaaklik van die laer ledemate met swelling, pyn en rooiheid.

U mag enige van hierdie simptome en/of toestande hê. Jy moet jou dokter so gou as moontlik vertel wanneer jy begin om enige van hierdie newe-effekte te ervaar.

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

Rapportering van newe-effekte
Indien u newe-effekte kry, bespreek dit met jou dokter, apteker of verpleegster.
Jy kan ook newe-effekte aanmeld aan SAHPRA via die "**6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting aangaande die veiligheid van PEXITAZ te verskaf.

5. Hoe om PEXITAZ te berg
Stoor alle medisyne buite die bereik van kinders.
Bewaar by of benede 25 °C (kamertemperatuur).
Moenie gebruik na die vervaldatum wat op die etiket en karton aangedui is nie.
Na hersamestelling moet PEXITAZ onmiddellik gebruik word. Indien voorberei soos aanbeveel, is die chemiese en fislese in-gebruik stabiliteit van die hersaamgeselde en oplossing vir infusie van PEXITAZ gedemonstreer vir 24 uur by yskastemperatuur.

6. Inhoud van die pak en ander inligting
Wat PEXITAZ bevat
- Die aktiewe bestanddeel is pemetreksed.
- Die ander bestanddele is: soutsuur, mannitol (suiker), suiwer stikstof, natriumhidroksied.

PEXITAZ 100
Elke flessie bevat 100 mg pemetreksed (as pemetreksed-dinatriumheptahidraat).
Bevat suiker: mannitol.

PEXITAZ 500
Elke flessie bevat 500 mg pemetreksed (as pemetreksed-dinatriumheptahidraat).
Die hersaamgestelde PEXITAZ-oplossing bevat 25 mg/ml pemetreksed**.**
Bevat suiker: mannitol.

Hoe PEXITAZ lyk en die inhoud van die pak
PEXITAZ 100:
Poeier vir oplossing vir infusie.
'n Wit tot ligte gee! of groen-geel geliofiliseerde poeier.
Elke karton bevat 'n 10 ml kleurlose tubulêre flessie met 'n grys rubber stopper en is met 'n ligte groen opknipdoppie, aan beide kante bedek met deursigtige lak, verseël.
PEXITAZ 500:
Poeier vir oplossing vir infusie.
'n Wit tot ligte gee! of groen-geel geliofiliseerde poeier.
Elke karton bevat 'n 50 ml kleurlose gevormde flessie met 'n grys rubber stopper en is met 'n ligte groen opknipdoppie, aan beide kante bedek met deursigtige lak, verseël.

Houer van Registrasiesertifikaat
RANBAXY PHARMACEUTICALS (PTY) LTD
'n Sun Pharma maatskappy
Lautre Weg 14, Stormill, Uitbreding 1,
Roodepoort, 1724
Suid Afrika

Die pamflet was hersien op

Registrasie nommers
PEXITAZ 100: 51/26/0231
PEXITAZ 500: 51/26/0232

Datum van registrasie: 14 Julie 2020