PATIENT INFORMATION LEAFLET
SCHEDULING STATUS: S4

NIVOCHA, 20 mg, 30 mg and 80 mg, Soft capsule

Vinorelbine tartrate

Contains sugar (sorbitol 12,40 mg, 18,70 mg and 34,5 mg respectively)

Contains less than 100 mg ethanol (alcohol) per 20 mg, 30 mg and 80 mg soft capsule.

Read all of this leaflet carefully before you start taking NIVOCHA

- 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.
- NIVOCHA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NIVOCHA is and what it is used for

NIVOCHA belongs to a group of medicines called vinca alkaloids and analogues; medicines that block cell growth by stopping mitosis (cell division).

NIVOCHA is used to treat:
- Non-small cell lung cancer
- Advanced breast cancer that has not responded to other medicines.

2. What you need to know before you take NIVOCHA

Do not take NIVOCHA:
- if you are hypersensitive (allergic) to vinorelbine, other vinca alkaloids or any of the other ingredients of NIVOCHA (listed in section 6),
- if you have a disease that significantly affects your gut (gastrointestinal) function,
- if you have previously had significant surgical resection (operation) of the stomach and small bowel,
- if you require long-term oxygen therapy,
- if you have recently received the yellow fever vaccine,
- if you have severe liver problems,
- if you have a low white blood cell count (neutrophils, granulocytes) or a severe infection current or recent within two weeks,
- if you are pregnant of breastfeeding your baby
- Safety and effectiveness in children have not been established

Warnings and precautions
Special care should be taken with NIVOCHA:
- when taking NIVOCHA, because chewing or sucking the capsule will cause severe irritation, rinse your mouth with water or preferably a normal saline solution, you should not swallow the damaged capsule and should be returned to the pharmacy or doctor in order to properly be destroyed.
- In case you vomit within a few hours after taking the medicine, do not take NIVOCHA again, NIVOCHA can easily cause nausea and vomiting. Taking anti-nausea medicine before taking NIVOCHA and also taking NIVOCHA with food is recommended, as this helps to reduce the incidence of nausea and vomiting.
- if you are taking NIVOCHA and being given morphine or opioid analgesics at the same time, because this may lead to constipation, your doctor may prescribe laxatives for you,
- if you have liver problems, because NIVOCHA may cause more bile pigment in blood
- if you have received or need a vaccination, the yellow fever vaccine or any other live attenuated vaccines, do not take NIVOCHA

Special care should be taken with NIVOCHA if:
- you have a history of heart attack or severe chest pain.
- you have problems with your liver, or you have received radiotherapy where the treatment field includes the liver.
- you have symptoms of infection (such as fever, chills, joint pain, cough).
- Before and during your treatment with **NIVOCHA** blood cell counts are performed to check that it is safe for you to receive treatment. If the results of this analysis are not satisfactory, your treatment may be delayed, and further checks made until these values return to normal.

Children and adolescents
Do not give NIVOCHA to children and adolescents safety has not been established.

Other medicines and NIVOCHA
Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Anticoagulants (medicines that helps prevent blood clots) - if you are being treated for a tumour, your healthcare provider may give you a prescription for anticoagulants while you are taking NIVOCHA, because there is an increased risk that blood clots will develop while you are taking NIVOCHA.
Your doctor may perform regular blood tests to see how long it takes your blood to clot.
Live attenuated vaccines - NIVOCHA should not be taken after you have received live attenuated vaccine, such as the yellow fever vaccine, as this may lead to death. Inform your doctor if you require any vaccinations.
Phenytoin (medicine used to treat epilepsy) - NIVOCHA should not be taken with phenytoin as this leads to its poor absorption, which could lead to an exacerbation of convulsions.
Cisplatin (medicine used to treat cancer) – NIVOCHA should not be taken with cisplatin as it may cause a significant decrease in granulocytes (a type of white blood cell in your blood).
Mitomycin C (medicine used to treat cancer) - NIVOCHA should not be taken with mitomycin C as there is a risk of lung infection that may affect your breathing.
Ciclosporin, tacrolimus (immunosuppressants) - NIVOCHA should not be taken with either ciclosporin or tacrolimus as this may compromise your immune system.
Itraconazole and ketoconazole (medicine used to treat fungal infections) - NIVOCHA should not be taken with itraconazole as this leads to a decrease in the metabolism of Itraconazole in the liver, which could result in an increase in the neurotoxicity of vinca-alkaloids.
The combination of NIVOCHA with other medicines with known bone marrow toxicity (affecting your white and red blood cells and your platelets) could also worsen some side effects.
Your doctor should take special attention if you are taking anti-tuberculosis medicine called rifampicin and an anti-epileptic medicine called phenytoin

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 this medicine.

You should stop taking NIVOCHA if you plan to become pregnant. Women of childbearing age should not use NIVOCHA unless they are reliably using highly effective contraception during treatment and up to 3 months after treatment. NIVOCHA should not be taken by pregnant or breastfeeding women.

Men being treated with NIVOCHA are advised not to father a child during and up to 3 months after the last capsule. You should discuss sperm banking with your doctor before starting treatment with NIVOCHA.

Driving and using machines
It is not always possible to predict to what extent NIVOCHA may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which NIVOCHA affects you.

NIVOCHA contains sorbitol and ethanol:
This medicine NIVOCHA 20 mg contains 5.36 mg sorbitol in each capsule.
This medicine NIVOCHA 30 mg contains 8.11 mg sorbitol in each capsule.
This medicine NIVOCHA 80 mg contains 14.91 mg sorbitol in each capsule.

This medicine NIVOCHA 20 mg contains 5 mg of alcohol (ethanol) in each capsule.
This medicine NIVOCHA 30 mg contains 7.5 mg of alcohol (ethanol) in each capsule.
This medicine NIVOCHA 80 mg contains 20 mg of alcohol (ethanol) in each capsule.

The amount in each capsule of this medicine (NIVOCHA 20 mg, 30 mg, 80 mg) is equivalent to less than 1 ml beer or 1 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take NIVOCHA

Do not share medicines prescribed for you with any other person.
Always take NIVOCHA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will decide on the number and strength of capsules you should receive for your condition and also for how long you need to receive it. The dose is calculated based on your body weight and body height. The dose and duration of treatment will depend on how your body reacts to the treatment.

NIVOCHA should be swallowed with water. Do not chew, suck or dissolve the capsule. It is recommended to take the capsule with some food as this has shown to reduce the incidence of nausea and vomiting.

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

If you take more NIVOCHA than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take NIVOCHA
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

NIVOCHA can have side effects.

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

If any of the following happens, stop taking NIVOCHA and tell your doctor immediately or go to the casualty department at your nearest hospital:
- serious allergic reactions such as swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- if you develop a rash or itching, fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to NIVOCHA. 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:
- anaemia (a low number of red blood cells in your blood with symptoms such as tiredness, lack of energy shortness of breath, irregular or fast heart beat),
- thrombocytopenia (a decreased number of blood platelets in your blood with symptoms such as easy and excessive bleeding, bruising easily and nose bleeds),
- shortness of breath,
- severe sepsis (a condition that occurs when your body has a strong immune response to an infection, which leads to widespread inflammation throughout the body) which can be fatal,
- pancytopenia (a decrease in the number of all types of blood cells with symptoms such as fatigue, weakness, bleeding problems, frequent infections, rapid heart rate, shortness of breath, headache) with marrow hypoplasia (a bone marrow disorder),
- heart problems caused by narrowed heart arteries
- gastrointestinal bleeding

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:
neutropenic infections (an infection resulting in a lack of certain white blood cells in your blood with symptoms such as fevers and frequent infections),
- reduction in blood cells (can only be seen when your doctor does blood tests),
- leucopenia (a decrease in the number of white blood cells in your blood with symptoms such as dizziness, fatigue, weakness, loss of appetite, low fever),
- loss of appetite,
- severe hyponatraemia (low level of soidum in the blood with symptoms such as nausea, headache, confusion and fatigue),
- insomnia (inability to sleep),
- loss of deep tendon reflexes (infrequently severe)
- headache,
- dizziness,
- visual impairment,
- heart failure and irregular heartbeat,
- abdominal pain,
- inflammation in the throat,
- difficulty in swallowing,
- liver disorders,
- alopecia (loss of hair from the head or body),
- pain in joints, or stiffness; difficulty in moving,
- muscle aching or cramping, muscle pain or stiffness; difficulty in moving,
- painful or difficult urination,
- vague feeling of bodily discomfort – body feels weak and tired,
- pain including pain at the tumour site,
- chills,
- weight loss, weight gain.
- nausea,
- vomiting,
- diarrhoea,
- inflammation of the mouth (sore mouth)
- constipation

Less frequent side effects:
- failure of muscular/muscle coordination
- paralytic ileus due to a bacterial or viral infection, is a condition that occurs when the muscle contractions that move food through your intestines are temporarily paralyzed
- nausea,
- vomiting,
- diarrhoea,
- inflammation of the mouth (sore mouth)
- constipation

Other significant side effects whose frequency is not known, but should be reported to your doctor immediately:
- syndrome of inappropriate antidiuretic hormone secretion (SIADH) (a condition in which high levels of the antidiuretic hormone (ADH) hormone cause the body to retain water),
- Heart attack (myocardial infarction)

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NIVOCHA.

5. How to store NIVOCHA

Store all medicines out of reach of children.

Store in a refrigerator (2 °C – 8 °C).

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NIVOCHA contains
The active substance is vinorelbine tartrate.

The other ingredients are anhydrous ethanol, purified water, glycerol and macrogol 400, gelatin, glycerol, partially dehydrated sorbitol liquid, titanium dioxide, ferric oxide yellow, ferric oxide red, purified water, printing ink, anyhydrous ethanol, medium-chain triglycerides, shellac glaze ~ 45 % (20 % esterified) in ethanol, isopropyl alcohol, ferrosoferric oxide/black iron oxide, n-butyl alcohol, propylene glycol and ammonium hydroxide 28 %.

What NIVOCHA looks like and contents of the pack
Soft capsule.
20 mg soft capsule: an oval-shaped, light brown, soft capsule with black “20” printed on the surface (for 20 mg) with the size of 9,0 ± 0,9 mm x 7,0 ± 0,7 mm.
30 mg soft capsule: an oblong-shaped pink soft capsule with black “30” printed on the surface (for 30 mg) with the size of 15,0 ± 1,5 mm x 6,0 ± 0,6 mm. 80 mg soft capsule: oblong-shaped pale yellow soft capsule with black “80” printed on the surface (for 80 mg) with the size of 20,0 ± 2,0 mm x 8,0 ± 0,8 mm.

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PASIËNTINLIGTINGSBLAD
SKEDULERINGSTATUS: S4

NIVOCHA, 20 mg, 30 mg en 80 mg, sagte kapsule
Vinorelbientartraat
Bevat suiker (12,40 mg, 18,70 mg en 34,5 mg sorbitol onderskeidelik)
Bevat minder as 100 mg etanol (alkohol) per 20 mg, 30 mg en 80 mg sagte kapsule.

Lees hierdie hele blad noukeurig deur voordat u begin om NIVOCHA te drink.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- NIVOCHA is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie blad is

1. Wat NIVOCHA is en waarvoor dit gebruik word

NIVOCHA behoort aan 'n groep medisyne genaamd vinka-alkaloïede en analoë; medisyne wat selgroei blokkeer deur mitose (seldeling) te stop.

NIVOCHA word gebruik om die volgende te behandel:
- Niekleinsel longkanker
- Gevorderde borskanker wat nie op ander medisyne gereageer het nie.

2. Wat u moet weet voordat u NIVOCHA drink

Moenie NIVOCHA drink nie:
- as u hipersensitief (allergies) vir vinorelbien, ander vinka-alkaloïede of vir enige van die ander bestanddele van NIVOCHA (gelys in afdeling 6) is.
- as u 'n siekte het wat u dermfunksie (gastro-intestinale funksie) beduidend beïnvloed,
- as u voorheen 'n beduidende chirurgiese reseksie (operasie) van die maag en dunderm gehad het,
- as u suurstof oor die lang termyn nodig het,
- as u onlangs die geelkoors-entstof ontvang het,
- as u erge lewerprobleme het,
- as u 'n lae witbloedseltelling (neutrofiele, granulosiete) of 'n erge infeksie het, wat tans of onlangs binne twee weke was,
- as u swanger is of u baba borsvoed.

Die veiligheid en doeltreffendheid vir kinders is nie bepaal nie.

Waarskuwings en voorsorgmaatreëls
Wees besonder versigtig met NIVOCHA:
- wanneer u NIVOCHA drink, aangesien die kou of suig van die kapsule erge irritasie sal veroorsaak; spoel u mond met water of verkieslik 'n normale soutoplossing uit. U moet nie die beskadigde kapsule insluk nie en dit moet na die apteek of dokter terugbesorg word om behoorlik vernietig te word.
- indien u binne 'n paar uur na die inname van die medisyne opbring, moet u NIVOCHA nie weer drink nie, want NIVOCHA kan maklik naarheid en braking veroorsaak. Dit word aanbeveel om 'n teenmiddel vir naarheid te gebruik voordat NIVOCHA gedrink word, asook om NIVOCHA saam met kos te drink, aangesien dit help om die voorkoms van naarheid en braking te verminder.
- as u NIVOCHA drink en terselfdertyd morfien of opioïedpynstillers kry, kan u dokter lakseermiddels vir u voorskryf, want dit kan tot hardlywigheid lei.
- as u lewerprobleme het, want NIVOCHA kan meer galpigment in die bloed veroorsaak.
- as u 'n inenting, die geelkoors-entstof of enige ander lewende verswakte entstowwe gekry of nodig het, moet u nie NIVOCHA drink nie.

Wees besonder versigtig met NIVOCHA as:
- u 'n geskiedenis van hartaanval of erge borspyn het.
- u probleme met u lewer het, of as u radioterapie ontvang het waar die behandelingsveld die lewer ingesluit het.
- u simptome van infeksie het (soos koors, kouekoors, gewrigspyn, hoes).

Voor en tydens u behandeling met NIVOCHA word bloedseltellings gedoen om te verseker dat dit veilig vir u is om behandeling te kry. Indien die resultate van hierdie analise nie bevredigend is nie, kan u behandeling uitgestel en verdere kontroles gedoen word totdat hierdie waardes na normaal teruggekeer het.

Kinders en adolessente
Moenie NIVOCHA vir kinders of adolessente gee nie, aangesien die veiligheid en effektiwiteit nie bepaal is nie.

Ander medisyne en NIVOCHA
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).
Antikoagulante (medisyne wat help om bloedklonte te voorkom) - as u vir 'n gewas behandel word, kan u gesondheidsorgverskaffer 'n voorskrif vir antikoagulante vir u gee terwyl u NIVOCHA drink, want daar is 'n hoë risiko dat bloedklonte sal ontwikkel terwyl u NIVOCHA drink.
U dokter mag gereelde bloedtoetse doen om te kyk hoe lank dit vir u bloed neem om te stol.
Lewende verswakte entstowwe - NIVOCHA moet nie gedrink word nadat u 'n lewende verswakte entstof, soos die geelkoorsentstof, gekry het nie, aangesien dit tot die dood kan lei. Sê vir u dokter as u enige entstowwe nodig het.
Fenitoïen (medisyne om epilepsie te behandel) - NIVOCHA moet nie saam met fenitoïen gedrink word nie, aangesien dit swak absorpsie kan veroorsaak, wat tot 'n verergering van stuiptrekkings kan lei.
Sisplatien (medisyne om kanker te behandel) – NIVOCHA moet nie saam met sisplatien gedrink word nie, aangesien dit 'n beduidende afname in die aantal granulosiete ('n tipe witbloedselle in u bloed) kan veroorsaak.
Mitomisien C (medisyne om kanker te behandel) - NIVOCHA moet nie saam met mitomisien C gedrink word nie, aangesien daar 'n risiko vir longinfeksie is wat u asemhaling kan beïnvloed.
Siklosporien, takrolimus (immuunonderdrukkers) - NIVOCHA moet nie saam met siklosporien of takrolimus gedrink word nie, aangesien dit u immuunstelsel kan benadeel.
Itrakonasool en ketokonasool (medisyne om swaminfeksies te behandel) - NIVOCHA moet nie saam met itrakonasool gedrink word nie, aangesien dit 'n afname in die metabolisme van itrakonasool in die lewer kan veroorsaak, wat tot 'n toename in die neurotoksisiteit van vinka-alkaloïede kan lei.
Die kombinasie van NIVOCHA met ander medisyne met bekende beenmurgtoksisiteit (wat u wit- en rooibloedselle en u bloedplaatjies beïnvloed) kan ook sommige newe-effekte vererger.
U dokter moet spesiale aandag gee as u 'n middel teen tuberkulose, genaamd rifampisien, en 'n anti-epileptiese middel, genaamd fenitoïen, gebruik.

Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidspraktisyn om advies raadpleeg voordat u hierdie medisyne gebruik.
U moet ophou om NIVOCHA te drink as u beplan om swanger te raak. Vroue van vrugbare ouderdom moet nie NIVOCHA gebruik nie, tensy hulle betroubare hoogs effektiewe voorbehoeding tydens behandeling en tot 3 maande na behandeling gebruik. NIVOCHA moet nie deur borsvoedende vroue gedrink word nie.
Mans wat met NIVOCHA behandel word, word aangeraai om tydens behandeling en tot 3 maande na die laaste kapsule nie 'n kind te verwek nie. U moet spermbankdienste met u dokter bespreek voordat u met behandeling met NIVOCHA begin.

Motorbestuur en gebruik van masjiene
Dit is nie altyd moontlik om te voorspel tot watter mate NIVOCHA met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u, totdat u weet tot watter mate NIVOCHA u aantas, nie betrokke raak by aktiwiteite wat verstandelike wakkerheid, goeie oordeel en/of gesonde koördinasie en visie vereis nie, bv. motorbestuur, ry, vlieg, seil of hanteer van masjiene/toerusting.

NIVOCHA bevat sorbitol en etanol
Hierdie medisyne, NIVOCHA 20 mg, bevat 5,36 mg sorbitol in elke kapsule.
Hierdie medisyne, NIVOCHA 30 mg, bevat 8,11 mg sorbitol in elke kapsule.
Hierdie medisyne, NIVOCHA 80 mg, bevat 14,91 mg sorbitol in elke kapsule.
Hierdie medisyne, NIVOCHA 20 mg, bevat 5 mg alkohol (etanol) in elke kapsule.
Hierdie medisyne, NIVOCHA 30 mg, bevat 7,5 mg alkohol (etanol) in elke kapsule.
Hierdie medisyne, NIVOCHA 80 mg, bevat 20 mg alkohol (etanol) in elke kapsule.
Die hoeveelheid alkohol in elke kapsule van hierdie medisyne (NIVOCHA 20 mg, 30 mg, 80 mg) is gelykstaande aan minder as dié in 1 ml bier of 1 ml wyn.
Die klein hoeveelheid alkohol in hierdie medisyne het geen merkbare effekte nie.

3. Hoe om NIVOCHA te drink

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
Drink NIVOCHA altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.
U dokter sal besluit oor die aantal en sterkte van die kapsules wat u vir u toestand moet kry en ook vir hoe lank u dit moet kry. Die dosis word bereken op grond van u liggaamsgewig en liggaamslengte. Die dosis en duur van die behandeling sal afhang van hoe u liggaam op die behandeling reageer.
NIVOCHA moet met vloeistof afgesluk word. Moenie die kapsule kou, suig of oplos nie. Dit word aanbeveel om die kapsule saam met kos te neem, aangesien dit aangetoon is dat dit die voorkoms van naarheid en braking verminder.
U dokter sal vir u sê hoe lank u behandeling met NIVOCHA sal duur. Sê vir u dokter of apteker as u die indruk het dat die effek van NIVOCHA te sterk of te swak is.

As u meer NIVOCHA gedrink het as wat u moes
Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om NIVOCHA te drink
Moenie 'n dubbele dosis drink om vir vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte

NIVOCHA kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir NIVOCHA aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u enige newe-effekte ervaar terwyl u NIVOCHA drink, moet u u gesondheidsorgverskaffer asseblief om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om NIVOCHA te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:
- ernstige allergiese reaksies soos swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak,
- as u 'n veluitslag of jeuk ontwikkel, flou word.

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige reaksie op NIVOCHA gehad het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:
- bloedarmoede ('n lae aantal rooibloedselle in u bloed met simptome soos moegheid, gebrek aan energie, kortasemheid, onreëlmatige of vinnige hartklop)
- trombositopenie ('n afname in die aantal bloedplaatjies in u bloed met simptome soos maklike en oormatige bloeding, maklike kneusing en neusbloeding),
- kortasemheid,
- erge sepsis ('n toestand wat voorkom wanneer u liggaam 'n sterk immuunrespons op 'n infeksie het, wat lei tot wydverspreide inflammasie regdeur die liggaam) wat dodelik kan wees,
- pansitopenie ('n afname in die aantal van alle soorte bloedselle met simptome soos moegheid, swakheid, bloedingprobleme, aanhoudende infeksies, vinnige hartklop, kortasemheid, hoofpyn) met murghipoplasie ('n beenmurgafwyking),
- hartprobleme veroorsaak deur vernoude hartslagare,
- gastro-intestinale bloeding.

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- neutropeniese infeksies ('n infeksie wat lei tot 'n gebrek aan sekere witbloedselle in u bloed met simptome soos koors en aanhoudende infeksies),
- afname in bloedselle (kan slegs gesien word wanneer u dokter bloedtoetse doen),
- leukopenie ('n afname in die aantal witbloedselle in u bloed met simptome soos duiseligheid, moegheid, swakheid, verlies aan eetlus, lae koors),
- verlies aan eetlus,
- erge hiponatremie (lae vlak van natrium in die bloed met simptome soos naarheid, hoofpyn, verwardheid en moegheid),
- slaaploosheid (onvermoë om te slaap),
- verlies van dieptendonreflekse (selde erg)
- hoofpyn,
- duiseligheid,
- swak visie,
- hartversaking of onreëlmatige hartklop,
- buikpyn,
- inflammasie in die keel,
- probleme met sluk,
- lewerversteurings,
- alopesie (verlies van hare van die kop of lyf),
- pyn of styfheid in die gewrigte, sukkel om te beweeg,
- spierpyn of -krampe, spierpyn of -styfheid; sukkel om te beweeg,
- pynlike of moeilike urinering,
- vae gevoel van liggaamlike ongemak – liggaam voel swak en moeg,
- pyn, waaronder pyn by die gewas,
- kouekoors,
- gewigsverlies, -toename,
- naarheid,
- braking,
- diarree,
- Inflammasie van die mond (seer mond),
- hardlywigheid.

Newe-effekte wat minder dikwels voorkom:
- mislukking van muskulêre-/spierkoördinasie,
- paralitiese ileus vanweë 'n bakteriële of virusinfeksie, 'n toestand wat voorkom wanneer die spiersametrekkings wat voedsel deur die ingewande beweeg, tydelik verlam word,
- naarheid,
- braking,
- diarree,
- inflammasie van die mond (seer mond),
- hardlywigheid,

Ander beduidende newe-effekte waarvan die frekwensie nie bekend is nie, maar wat onmiddellik by u dokter aangemeld moet word:
- sindroom van onvanpaste afskeiding van antidiuretiese hormoon (SOAADH) ('n toestand waarin hoë vlakke van die antidiuretiese hormoon (ADH) veroorsaak dat die liggaam water behou),
- hartaanval (miokardiale infarksie).

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegkundige as u newe-effekte ervaar. U kan newe-effekte ook by SAHPRA aanmeld via die Med Safety-toep (Medsafety X SAHPRA) en eReporting-platform (who-umc.org) wat op SAHPRA se webwerf gekry kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van NIVOCHA te gee.

5.Hoe om NIVOCHA te bêre

Hou alle medisyne buite bereik van kinders.
Bêre in 'n yskas (2 tot 8 ºC).
Gee alle ongebruikte medisyne terug aan u apteker.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6.Inhoud van die pak en ander inligting

Wat NIVOCHA bevat Wat NIVOCHA bevat
Die aktiewe bestanddeel is vinorelbientartraat.
Die ander bestanddele is watervrye etanol, gesuiwerde water, gliserol en makrogol 400, gelatien, gliserol, gedeeltelik gedehidreerde sorbitolvloeistof, titaandioksied, geel ysteroksied, rooi ysteroksied, gesuiwerde water, drukkersink, watervrye etanol, mediumketting-trigliseriede, skilferglans ~ 45% (20% veresterd) in etanol, isopropielalkohol, ferrosoferi-oksied/swart ysteroksied, n-butielalkohol, propileenglikol en 28% ammoniumhidroksied.

Hoe NIVOCHA lyk en die inhoud van die pakkie
Sagte kapsule.
Sagte kapsule van 20 mg: 'n ovaalvormige, ligbruin, sagte kapsule met "20" in swart op die oppervlak gedruk (vir 20 mg) met die grootte van 9,0 ± 0,9 mm x 7,0 ± 0,7 mm.
Sagte kapsule van 30 mg: 'n ovaalvormige, ligbruin, sagte kapsule met "30" in swart op die oppervlak gedruk (vir 30 mg) met die grootte van 15,0 ± 1,5 mm x 6,0 ± 0,6 mm.
Sagte kapsule van 80 mg: 'n ovaalvormige, ligbruin, sagte kapsule met "80" in swart op die oppervlak gedruk (vir 80 mg) met die grootte van 20,0 ± 2,0 mm x 8,0 ± 0,8 mm.

Houer van die registrasiesertifikaat
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Hierdie blad is laas hersien op
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80 mg: 57/26/0399