Olanzapine Tablets Leaflate Front

340 mm

410 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

NEZOLAP 2,5 mg (Film-coated tablet)
NEZOLAP 5 mg (Film-coated tablet)
NEZOLAP 10 mg (Film-coated tablet)
Olanzapine 2,5 mg, 5 mg and 10 mg
Sugar free

NEZOLAP ODT 5 mg (orally disintegrating tablet) Contains aspartame (0,125 mg)
NEZOLAP ODT 10 mg (orally disintegrating tablet) Contains aspartame (0,25 mg)
NEZOLAP ODT 15 mg (orally disintegrating tablet) Contains aspartame (0,375 mg)
NEZOLAP ODT 20 mg (orally disintegrating tablet) Contains aspartame (0,50 mg)
Olanzapine 5 mg, 10 mg, 15 and 20 mg

Read all of this leaflet carefully before you start taking NEZOLAP
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **NEZOLAP** 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 **NEZOLAP** is and what it is used for
2. What you need to know before you take **NEZOLAP**
3. How to take **NEZOLAP**
4. Possible side effects
5. How to store **NEZOLAP**
6. Contents of the pack and other information

1. What NEZOLAP is and what it is used for

NEZOLAP belongs to a group of medicines called antipsychotics.
NEZOLAP is used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.
NEZOLAP is also used to treat moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.

2. What you need to know before you take NEZOLAP

Do not take NEZOLAP:
- If you are allergic to olanzapine or any of the ingredients of **NEZOLAP** (listed in section 6).
- If you have been previously diagnosed with eye problems such as certain types of glaucoma (increased pressure in the eye)
- If you are younger than 18 years of age.

Warnings and precautions
Tell your doctor or healthcare professional before you take **NEZOLAP:**
- about any past or present medical problems
- about any risk factors for heart disease or if you have a family history of heart disease
- if you have high blood pressure or diabetes
- if you smoke
- about any allergies you have or have had
- if you have epilepsy
- if you have kidney or liver disease
- if you have Parkinson's disease
- if you have prostate problems
- if you have a blocked intestine (Paralytic ileus)
- if you suffer from any blood disorders
- if you have had a stroke recently
- if you are elderly and suffer from dementia.

While taking NEZOLAP:
- You may experience an increase in blood sugar (hyperglycaemia). If you have diabetes already or are at risk of becoming diabetic (e.g. family history or being overweight, your doctor will conduct tests to check your blood sugar before you start taking **NEZOLAP** and during treatment. In people who do not have diabetes, high blood sugar might go away when **NEZOLAP** is stopped. People with diabetes and some people who did not have diabetes before taking **NEZOLAP** may need to take medicine for high blood sugar even after they stop taking **NEZOLAP.**
- If you suddenly stop taking **NEZOLAP,** symptoms such as sweating, diarrhoea, drooling, unable to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest that you reduce the dose gradually before stopping treatment.
- **NEZOLAP** may cause a combination of fever, faster breathing, sweating, muscle stiffness, irregular or rapid heartbeat, irregular pulse or blood pressure. If you experience any of these symptoms, stop taking **NEZOLAP** and inform your doctor.
- **NEZOLAP** may cause unusual movements mainly of the face or tongue. If this happens after you have been given **NEZOLAP** tell your doctor.
- High levels of fat (triglycerides and cholesterol) have been seen in patients taking **NEZOLAP.** Your doctor should do blood tests to check certain fat levels before you start taking **NEZOLAP** and regularly during treatment.
- Tell your doctor if you or someone else in your family has a history of blood clots, as medicines like **NEZOLAP** have been associated with formation of blood clots.
- **Tell** your doctor if you experience light headedness or fainting caused by a sudden change in heart rate and blood pressure when rising too quickly from a sitting or lying position.
- Problems with control of body temperature: You could become very hot, for instance when you exercise a lot or stay in an area that is very hot. It is important for you to drink water to avoid dehydration. **Call** your doctor right away if you become severely ill and have any of these symptoms of dehydration
  - sweating too much or not at all
  - dry mouth
  - feeling very hot
  - not able to produce urine
  - feeling thirsty.
- **NEZOLAP** may cause difficulty swallowing that can cause food or liquid to get into your lungs.
- The symptoms of schizophrenia may include thoughts of suicide or of hurting yourself or others. If you have these thoughts at any time, tell your doctor or go to casualty at your nearest hospital right away.

Children and adolescents
NEZOLAP is not for patients who are under 18 years.

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

Only take other medicines while you are on **NEZOLAP** if your doctor **tells** you that you can. You might feel drowsy if **NEZOLAP** is taken in combination with alcohol, antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).
You should **tell** your doctor if you are taking the following medicines as it may be necessary to change your **NEZOLAP** dose:
- fluoxetine or fluvoxamine (antidepressants)
- ciprofloxacin (an antibiotic)
- ketoconazole (an antifungal medicine)
- carbamazepine (for epilepsy)
- aripiprazole (for mental illness)
- pramipexole, ropinirol, levodopa (for Parkinson's disease)
- activated charcoal

Tell your doctor if you are taking the following medicines which may affect the rhythm of the heart as these should not be taken with **NEZOLAP.**
- medicines that belong to the group of antidysrhythmics (e.g. quinidine, hydroquinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide, ibutilide).
- antipsychotics (e.g. phenothiazines, pimozide, sertindole, haloperidol, sulpiride).
- tricyclic antidepressants (amitriptyline, imipramine, dothiepin, trimipramine, desimipramine).
- antimicrobial medicines (erythromycin, sequinavir, sparfloxacin, pentamidine, amphotericin B, moxifloxacin)
- antimalarials (halofantrine)
- antihistamines (astemizole, mizolastine)

Tell your doctor if you are taking medicines for high blood pressure as the blood pressure lowering effect may be enhanced when used together with **NEZOLAP.**

NEZOLAP with food and drink and alcohol:
NEZOLAP can be taken with or without food. Do not drink any alcohol while taking **NEZOLAP** as the alcohol together with **NEZOLAP** will make you drowsy.

Pregnancy, breastfeeding and fertility
Safety in pregnancy and breastfeeding has not been established.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **NEZOLAP.**
The following symptoms may occur in newborn babies, of mothers that have used **NEZOLAP** in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you should contact your doctor.

You should not breastfeed your baby if you are taking **NEZOLAP,** as small amounts of olanzapine can pass into breast milk.
Driving and using machines
Dizziness and drowsiness have been reported in patients receiving **NEZOLAP.** It is not always possible to predict to what extent **NEZOLAP** may interfere with the daily activities of a patient. You should not engage in the above activities until you are aware of the measure to which **NEZOLAP** affects you.

NEZOLAP ODT contains phenylalanine
Patients who cannot take phenylalanine should note that **NEZOLAP ODT** contains aspartame, which is a source of phenylalanine. May be harmful for people with phenylketonuria.

3. How to take NEZOLAP

Do not share medicines prescribed for you with any other person.
Always take **NEZOLAP** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
The usual dose of **NEZOLAP** is between 5 and 20 mg daily.
Your doctor **will tell** you how long your treatment with **NEZOLAP** will last. Do not stop treatment early. If you have the impression that the effect of **NEZOLAP** is too strong or too weak, tell your doctor or pharmacist.
Take the tablets with a sufficient quantity of liquid (e.g. one glass of water)
Take **NEZOLAP** once a day, every day. Try to take your tablets at the same time each day. It will also help you remember when to take the tablets.
NEZOLAP ODT is a rapid-dispersing preparation to be placed in the mouth or alternatively to be dispersed in water or other suitable beverage for administration.

NEZOLAP ODT should be placed in the mouth, where they will rapidly disperse in the saliva, so they can be easily swallowed. Removal of the intact orodispersible tablet from the mouth is difficult. Since the orodispersible tablet is fragile, it should be taken immediately on opening the blister. Alternatively, it may be dispersed in a full glass of water or suitable beverage (orange juice, apple juice, milk or coffee) immediately before administration.

If you take more NEZOLAP than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Patients who have taken more **NEZOLAP** than they should may experience the following symptoms: rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness. Other symptoms may be: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart.

If you forget to take NEZOLAP
Take your tablets as soon as you remember. Do not take a double dose to make up for forgotten individual doses. Do not take two doses in one day.

If you stop taking NEZOLAP
Do not stop taking your tablets just because you feel better. It is important that you carry on taking **NEZOLAP** for as long as your doctor tells you.
If you suddenly stop taking **NEZOLAP,** symptoms such as sweating, inability to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you to reduce the dose gradually before stopping treatment.

4. Possible side effects

NEZOLAP can have side effects.
Not **all** side effects reported for **NEZOLAP** are included in this **leaflet.** Should your general health worsen or if you experience any unloward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **NEZOLAP** and **tell** your doctor immediately or go to the casualty department at your nearest hospital:
- **Allergic reaction.** Symptoms of a severe allergic reaction such as:
  - Swelling of face, tongue or throat
  - Difficulties in swallowing
  - Hives and difficulties in breathing
  - Severe skin reactions that can include blistering of the skin.
- **Blood clots in the veins especially in the legs** (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms, seek medical advice immediately.
- Thoughts of suicide
- **Diabetic ketoacidosis** (symptoms include excessive thirst or urination, nausea and vomiting, abdominal pain, loss of appetite, shortness of breath, fruity-scented breath, confusion).
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) DRESS can occur with **NEZOLAP.** Features of DRESS may include rash, fever, swollen glands and other internal organ involvement such as liver, kidney, lung and heart. DRESS is sometimes fatal; therefore, tell your doctor immediately if you experience any of these signs.

These are all very serious side effects. If you have them, you may have had a serious reaction to **NEZOLAP.** 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:
- Lowering of normal body temperature.
- Seizures.
- Abnormal rhythms of the heart (slow or fast).
- Inflammation of the pancreas causing severe stomach pain, fever and sickness.
- Liver disease appearing as yellowing of the skin and white parts of the eyes.
- Muscle disease presenting as unexplained aches and pains.
- Difficulty in passing urine.
- Prolonged and/or painful erection.
- While taking **NEZOLAP,** elderly patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and have trouble walking.

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:
- Bruising, increase in some white blood cells, lack of white blood cells.
- Swelling of the hands and feet, weight gain, high cholesterol levels in the blood, high sugar levels in the blood, high levels of certain fats in the blood, increased appetite.
- Sleepiness, dizziness, inability to sit still, increase in parkinsonian symptoms — such as tremor, slow movement, impaired speech or muscle stiffness.
- In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.
- Constipation, dry mouth
- Joint pain.
- Sexual dysfunction such as decreased libido in males and females or erectile dysfunction in males, abnormal ejaculation.
- Unusual tiredness or weakness, fever, swelling.
- Elderly patients with dementia may suffer from pneumonia, urinary incontinence, falls, have trouble walking.

Less frequent side effects:
- Low blood platelet count resulting in bleeding or bruising more easily than normal.
- Involuntary contraction of muscles, involuntary upward deviation of the eyes, loss of memory, slurred or slow speech, stuttering, irresistible urge to move the legs.
- Nosebleed.
- Bloating and swelling in the belly area.
- Fatty deposits in the liver (symptoms include loss of appetite, weight loss, weakness, fatigue, nosebleeds, itchy skin, yellow skin and eyes).
- Rash, redness of the skin due to sun exposure, hair loss.
- Painful or difficult urination, the need to urinate many times during the day and night, inability to completely or partially empty the bladder, passing more urine than normal.
- **NEZOLAP** may cause neonatal drug withdrawal syndrome which happens when babies are exposed to medicines in the womb before birth. Babies are then affected or go through drug withdrawal after birth. Signs of newborn drug withdrawal include blotchy skin, diarrhoea, fussiness, fever, vomiting, tremors, and slow development.
- Absence or decrease in menstrual periods, changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Blood test may show increased liver enzymes, increased prolactin, increased alkaline phosphatase, high creatine phosphokinase, high gamma glutamyltransferase, high uric acid and increased total bilirubin.

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 **NEZOLAP.**

5. How to store NEZOLAP

Store at or below 25 °C (room temperature). Protect from light.
Store all medicines out of reach of children.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Keep the HDPE containers tightly closed.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What NEZOLAP contains
- The active substance is olanzapine 2,5 mg, 5 mg and 10 mg.
- The other ingredients are microcrystalline cellulose, low substituted hydroxypropyl cellulose, crospovidone, and magnesium stearate, coating agent containing polyvinyl alcohol partly hydrolysed, titanium dioxide (CI 77891), talc, lecithin (soya), and xanthan gum.

What NEZOLAP ODT contains
- The active substance is olanzapine 5 mg, 10 mg, 15 mg and 20 mg. The other ingredients are
- Contains aspartame, crospovidone, low substituted hydroxypropyl cellulose (L-HPC-LH-11), magnesium stearate and microcrystalline cellulose

What NEZOLAP looks like and contents of the pack
NEZOLAP 2,5 mg:
White to off white coloured, round shaped, biconvex, film-coated tablets having 'CL' debossed on one side and '39' debossed on other side.
NEZOLAP 5 mg:
White to off white coloured, round shaped, biconvex, film-coated tablets having 'CL 40' debossed on one side and plain on other side.
NEZOLAP 10 mg:
White to off white coloured, round shaped, biconvex, film-coated tablets having 'CL 42' debossed on one side and plain on other side.
NEZOLAP ODT 5 mg
Yellow, round shaped, biconvex, uncoated tablets having 'ML 35' debossed on one side and plain on other side.
NEZOLAP ODT 10 mg:
Yellow, round shaped, biconvex, uncoated tablets having 'ML 36' debossed on one side and plain on other side.
NEZOLAP ODT 15 mg:
Yellow, round shaped, biconvex, uncoated tablets having 'ML 37' debossed on one side and plain on other side.
NEZOLAP ODT 20 mg:
Yellow, round shaped, biconvex, uncoated tablets having 'CL 1' debossed on one side and plain on other side.

1) Blister Pack:
NEZOLAP and NEZOLAP ODT are packed in cold form laminate 25 µ OPA/ 45 µ aluminium foil / 60 µ PVC as the forming material and 25 µ Aluminium plain foil/ 6-8 grams heat seal lacquered as the lidding material, packed in a pre-printed carton.
Pack size include 10, 28 or 30 tablets.

2) HDPE Container Pack:
NEZOLAP Tablets are packed in 60 ml white round HDPE container with 33 mm neck finish which are closed with 33 mm child resistant closure with pulp and heat seal liner and packed in outer carton. Each HDPE container contains 1 sachet of 1 g silica gel.
NEZOLAP ODT are packed in 40 ml or 60 ml white round HDPE container with 33 - 400 mm neck finish which are closed with 33 mm child resistant closure with pulp and heat seal liner and packed in outer carton. Each HDPE container contains 1 sachet of 1 g silica gel.
Pack size include 28 or 30 tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
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Alberton, South Africa.

This leaflet was last revised in
23 March 2021

Registration number
NEZOLAP 2,5 mg: 47/2.6.5/0284
NEZOLAP 5 mg: 47/2.6.5/0285
NEZOLAP 10 mg: 47/2.6.5/0286
NEZOLAP ODT 5 mg: 48/2.6.5/0343
NEZOLAP ODT 10 mg: 48/2.6.5/0344
NEZOLAP ODT 15 mg: 48/2.6.5/0345
NEZOLAP ODT 20 mg: 48/2.6.5/0346

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://medicedssaproducts.co.za/ or contact 011 682 1169

NEZOLAP
PM/2826/360

Olanzapine Tablets Leaflate Back

340 mm

410 mm

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

NEZOLAP 2,5 mg (Filmbedekte Tablet)
NEZOLAP 5 mg (Filmbedekte Tablet)
NEZOLAP 10 mg (Filmbedekte Tablet)
Olansapien 2,5 mg, 5 mg en 10 mg
Suikervry

NEZOLAP ODT 5 mg (orale disintegreerbare tablet) Bevat aspartaam (0,125 mg)
NEZOLAP ODT 10 mg (orale disintegreerbare tablet) Bevat aspartaam (0,25 mg)
NEZOLAP ODT 15 mg (orale disintegreerbare tablet) Bevat aspartaam (0,375 mg)
NEZOLAP ODT 20 mg (orale disintegreerbare tablet) Bevat aspartaam (0,50 mg)
Olansapien 5 mg, 10 mg, 15 mg en 20 mg

Lees hierdie hele inligtingsblad aandagtig deur, voordat jy NEZOLAP begin gebruik
- Hou hierdie inligtingsblad. Dit mag wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of apteker.
- **NEZOLAP** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander mense te deel nie. Selfs al het hulle dieselfde simptome as jy, kan dit vir hulle skadelik wees.

Wat in hierdie inligtingsblad is
1. Wat **NEZOLAP** is en waarvoor dit gebruik word,
2. Wat jy behoort te weet voordat jy **NEZOLAP** gebruik.
3. Hoe om **NEZOLAP** te neem
4. Moontlike newe-effekte
5. Hoe om **NEZOLAP** te berg
6. Inhoud van die pak en ander inligting

1. Wat NEZOLAP is en waarvoor dit gebruik word

NEZOLAP behoort aan 'n groep medisyne wat antipsigotiese middels genoem word. **NEZOLAP** word gebruik om 'n siekte te behandel met simptome soos om dinge wat nie bestaan nie te hoor, te sien, of aan te voel, verkeerde oortuigings, ongewone agterdog, en teruggetrokkenheid. Mense met hierdie siekte kan ook depressief, angstig of gespanne voel.
NEZOLAP word ook gebruik vir die behandeling van matige tot erge manlese episodes, 'n toestand met simptome van opgewondenheid of welbehaaglikheid.

2. Wat jy behoort te weet voordat jy NEZOLAP neem

Moet nie NEZOLAP neem nie:
- Indien jy allergies is vir olansapien of enige van die ander bestanddele van **NEZOLAP** (gelys in afdeling 6).
- Indien jy voorheen gediagnoseer is met oogprobleme soos sekere tipes van gloukoom (verhoogde druk in die oog).
- Indien jy jonger as 18 jaar oud is.

Waarskuwings en voorsorgmaatreëls
Vertel jou dokter of gesondheidsorgwerker voordat jy **NEZOLAP** neem:
- oor enige mediese probleme in die verlede of tans
- oor enige nakie faldore vir hartsiekte of indien jy 'n familiegeskiedenis van hartsiekte het
- indien jy hoë bloeddruk of diabetes het
- indien jy rook
- oor enige allergieë wat jy het of gehad het
- as jy epilepsie het
- as jy nier- of leversiekte het
- indien jy Parkinson se siekte het
- as jy probleme met jou prostaat het
- indien jy 'n verstopte dunderm het (Paralitiese ileus)
- as jy aan enige bloedafwykings ly
- indien jy onlangs 'n beroerte gehad het
- as jy 'n bejaarde is en aan demensie ly.

Terwyl NEZOLAP geneem word:
- Jy kan 'n toename in bloedsuiker (hiperglukemie) ervaar. Indien jy alreeds diabetes het of die nakie loop om diabetes te word (bv. familiegeskiedenis of oorgewig), sal jou dokter toetse doen om jou bloedsuiker te kontroleer voordat jy **NEZOLAP** begin gebruik en tydens die behandeling. In mense wat nie diabetes het nie, kan hoe bloedsuiker weggaan wanneer **NEZOLAP** gestaak word. Mense met diabetes en sommige mense wat nie diabetes gehad het voordat hulle **NEZOLAP** begin neem het nie, sal moontlik medisyne moet neem vir hoë bloedsuiker, selfs nadat hulle ophou om **NEZOLAP** te gebruik.
- Indien jy skielik ophou om **NEZOLAP** te neem, kan simptome soos sweet, diarree, lwyt, slaaploosheid, bewing, angs of naarheid en braking voorkom. Jou dokter kan voorstel dat jy die dosis geleidelik verminder voordat jy met die behandeling stop.
- **NEZOLAP** kan 'n kombinasie van koors, vinniger asemhaling, sweet, spierstyfheid, onreëlmatige of vinnige hartslop, onreëlmatige pols of bloeddruk veroorsaak. As jy enige van hierdie simptome ervaar, moet jy ophou om **NEZOLAP** te neem en jou dokter in kennis stel.
- **NEZOLAP** kan ongewone bewegings veroorsaak, veral van die gesig of long. As dit gebeur nadat **NEZOLAP** aan jou gegee is, moet jy dit aan jou dokter vertel.
- Hoë vlakke van vet (triglisenede en cholesterol) is al gesien in pasiënte wat **NEZOLAP** gebruik. Jou dokter behoort bloedtoetse te doen om sekere vetvlakke te kontroleer voordat jy **NEZOLAP** begin neem en gereeld tydens die behandeling.
- Vertel jou dokter indien jy of iemand anders in jou familie 'n geskiedenis van bloedklonte het, omdat medisyne soos **NEZOLAP** geassosieer word met die vorming van bloedklonte.
- Vertel jou dokter indien jy ligkoofdigheid of floute ervaar, veroorsaak deur 'n skielike verandering in harttempo en bloeddruk, wanneer jy te vinnig vanuit 'n sit- of lêposisie opstaan.
- Probleme met die beheer van liggaamstemperatuur: jy kan bae warm word, byvoorbeeld as jy baie oefen of in 'n baie warm gebied bly. Dit is belangrik dat jy water drink om dehidrasie te voorkom. Skakel onmiddellik jou dokter as jy ernstig siek word en enige van die volgende simptome van dehidrasie het:
  - sweet te veel of gled nie
  - droë mond
  - voel bae warm
  - nie in staat om urine te produseer nie
  - voel dors.
- **NEZOLAP** kan probleme met sluit veroorsaak wat kan veroorsaak dat koe of voedsel in jou longe beland.
- Die simptome van slaschrone kan gedagtes van selfmoord of om jouself of ander seer te maak insluit. As jy op enige tydstip hierdie gedagtes ervaar, vertel dit aan jou dokter of gaan dadelik na die ongevalle afdeling van jou naaste hospitaal..

Kinders en adolessente
NEZOLAP is nie vir pasiënte jonger as 18 jaar oud nie.

Ander medisyne en NEZOLAP
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).

Neem slegs ander medisyne terwyl jy op **NEZOLAP** is, indien jou dokter sê dat jy kan. Jy kan moontlik lomerig voel indien **NEZOLAP** geneem word in kombinasie met alkohol, antidepressante of medisyne wat gebruik word vir angsigheid of om jou te help slaap (kalmeermiddels).

Jy behoort jou dokter te vertel indien jy die volgende medisyne neem, aangesien dit mag nodig wees om jou **NEZOLAP** dosering te verander:
- fluoksetien of fluvoksamien (antidepressante)
- siprofloksasien ('n antibiotika)
- ketokonasool ('n antifungusmiddel)
- karbamasepien (vir epilepsie)
- antipsigotiese (vir geestesongesteldheid)
- prampeksool, ropinirol, levodopa (vir Parkinson se siekte)
- geaktiveerde houtskool

Vertel jou dokter indien jy die volgende medisyne gebruik wat die ritme van die hart kan beïnvloed, aangesien dit nie saam met **NEZOLAP** geneem moet word nie:
- medisyne wat tot die antidysritmiese groep middels behoort (bv. kinidien, hidrokinidien, disopiramied, prokaïenamied, amiodaron, sotalol, dofetilied, ibutilied).
- antipsigotiese middels (bv. fenotiasiene, pimosied, sertindool, haloperidol, sultopried).
- trisiklese antidepressante (amitriptilien, imipramien, dosipien, trimipramien. desimipramien).
- antimikrobemiddels (eritromisien, sakwinavir, sparfloksasin, pentamidien, amfoterisien B, moksifloksasien)
- antimelanienmiddels (halofantrien)
- antihistamiekums (astemisool, mesolastien)

Vertel jou dokter indien jy medisyne vir hoë bloeddruk gebruik, aangesien die bloeddrukverlagende effek verhoog kan word wanneer dit saam met **NEZOLAP** gebruik word.

NEZOLAP met voedsel en drankies en alkohol:
NEZOLAP kan met of sonder voedsel geneem word. Moet nie enige alkohol drink terwyl jy **NEZOLAP** gebruik nie, aangesien die alkohol saam met **NEZOLAP** jou lomerig sal maak.

Swangerskap, borsvoeding en fertiliteit
Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy **NEZOLAP** neem.
Die volgende simptome kan voorkom in pasgebore babas van moeders wat **NEZOLAP** in die laaste trimester (laaste drie maande van hul swangerskap) gebruik het: bewe, spierstyfheid en/of -swakheid, slaperigheid, rusteloosheid, asemhalingsprobleme en probleme met voeding. Indien jou baba enige van hierdie simptome ontwikkel, moet jy jou dokter kontak.

Jy moet nie jou baba borsvoed as jy **NEZOLAP** neem nie, omdat klein hoeveelhede van olansapien in borsmelk kan oorgaan.

Bestuur en gebruik van masjinerie
Duiseligheid en lomerigheid is aangemeld in pasiënte wat **NEZOLAP** ontvang. Dit is nie altyd moontlik om te voorspel in watter mate **NEZOLAP** die dagliikse aktiwiteite van 'n persoon kan beïnvloed nie. Jy moet nie een bogenoemde aktiwiteite deelneem totdat jy weet tot watter mate **NEZOLAP** jou beïnvloed nie.

NEZOLAP ODT bevat fenielalanien
Pasiënte wat nie fenielalanien kan gebruik nie, moet daarop let dat **NEZOLAP ODT** aspartaam bevat, wat 'n bron van fenielalanien is. Kan skadelik wees vir mense met **fenielketonurie.**

3. Hoe om NEZOLAP te neem

Moet nie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Neem altyd **NEZOLAP** presies soos jou dokter jou opdrag gegee het. Vra jou dokter of apteker indien jy onseker is.
Die gewone dosis van **NEZOLAP** is tussen 5 en 20 mg per dag.
Jou dokter sal jou vertel hoe lank jou behandeling met **NEZOLAP** sal duur. Moet nie met die behandeling vroeër ophou nie. Indien jy onder die indruk is dat die effek van **NEZOLAP** te sterk of te swak is, praat dan met jou dokter of apteker.
Neem die tablette met 'n voldoende hoeveelheid vloeistof (bv. een glas water).
Neem **NEZOLAP** een keer per dag, elke dag. Probeer om jou tablette op dieselfde tyd elke dag te neem. Dit sal jou ook help om te onthou wanneer jy jou tablette moet neem.
NEZOLAP ODT is 'n vinnig oplosbare voorbereiding wat in die mond geplaas, of alternatiewelik in water of 'n ander geskikte drankie opgelos kan word vir toediening.

NEZOLAP ODT moet in die mond geplaas word, waar dit vinnig in die speeksel sal oplos, sodat dit maklik geslulk kan word. Verwydering van die ongeskonde mondelingse oplosbare tablet uit die mond is moeilik. Aangesien die mondelingse oplosbare tablet baie bros is, behoort dit onmiddellik nadat die stulpstrook oopgemaak is, geneem te word. Dit kan alternatiewelik opgelos word in 'n vol glas met water of gepaste drankie (lemoensap, appelsap, melk of koffie) onmiddellik voor toediening.

As jy meer NEZOLAP neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Pasiente wat meer **NEZOLAP** geneem het as wat hulle behoort te neem, kan die volgende simptome ervaar: vinnige hartslop, opgewondenheid/aggressiwiteit, probleme met spraak, ongewone bewegings (veral van die gesig of long) en verminderde bewussynsvlak. Ander simptome kan wees: akute verwarring, aanvalle (epilepsie), koma, 'n kombinasie van koors, vinniger asemhaling, sweet, spierstyfheid en lomerigheid of slaperigheid, vertraagde asemhalingstempo, aspirasie, hoë bloeddruk of lae bloeddruk, abnormale harttrime.

Indien jy vergeet om NEZOLAP te neem
Neem jou tablette sodra jy daarvan onthou. Moet nie 'n dubbele dosis neem om vir die vergete individuele dosisse op te maak nie. Moet nie twee doserings in een dag neem nie.

As jy ophou om NEZOLAP te neem
Moet nie ophou om jou tablette te neem, net omdat jy beter voel nie. Dit is belangrik dat jy aanhou om **NEZOLAP** te neem vir so lank as wat jou dokter jou sê om dit te doen.
As jy skielik ophou om **NEZOLAP** te gebruik, kan simptome soos sweet, onvermoë om te slaap, bewing, angs of naarheid en braking voorkom. Jou dokter kan dalk voorstel dat jy die dosis geleidelik moet verminder voordat jy met die behandeling ophou.

4. Moontlike newe-effekte

NEZOLAP kan newe-effekte hê.
Nie alle newe-effekte wat vir **NEZOLAP** aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verslag of indien jy enige ongunstige effekte ervaar terwyl jy hierdie medisyne neem, kontak asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.
Indien enige van die volgende gebeur, hou op om **NEZOLAP** te neem, en vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal
- **Allergiese reaksie.** Simptome van 'n erge allergiese reaksie sooe:
  - Swelling van die gesig, long of keel
  - Moeilike asemhaling
  - Netelroes en probleme met asemhaling
  - Erge velreaksies wat blase van die vel kan insluit.
- **Bloedklonte** in die are, wat in die bene (simptome sluit in swelling, pyn en rooiheid in die been), wat moontlik deur die bloedvate na die longe kan beweeg en borskaspyn en moeilike asemhaling kan veroorsaak. As jy enige van hierdie simptome opmerk, moet jy dadelik mediese advies inwin.
- **Gedagtes van selfmoord**
- **Diabetiese ketoasidose** (simptome sluit in oormatige dors of urinering, naarheid en braking, abdominale pyn, selfuswerlies, kortasem, vrugte-geurige asem, verwarring).
- **Geneesmiddelreaksie met eosinofilie en sistemiese simptome** (GRESS) GRESS kan voorkom met **NEZOLAP.** Kenmerke van GRESS kan uitslag, koors, geswelde kliers en ander inwendige organe sooe lewer, nier, long en hart insluit. GRESS is soms noodlotlig, vertel dit dus onmiddellik aan jou dokter indien jy enige van hierdie tekens ervaar.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige reaksie op **NEZOLAP** gehad. Jy benodig moontlik dringende mediese hulp of hospitaalsasie.

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal, indien jy enige van die volgende opmerk:
- Verlaging van normale liggaamstemperatuur.
- Aanvalle,
- Abnormale harttrimes (stadig of vinnig).
- Ontsteking van die pankreet wat erge maagpyn, koors en siekte veroorsaak.
- Leversiekte wat verskyn as vergeling van die vel en wit dele van die oë.
- Spiersiekte wat verskyn as onverklaarbare pyne en skete.
- Probleme om te urineer.
- Longdrange en/of pynlike ereksie.
- Terwyl **NEZOLAP** geneem word, kan bejaarde pasiënte met demensie jy aan beroerte, longontsteking, urinêre inkontinensie, valle, uiterste moegheid, vreuele hallusinasies, 'n toename in liggaamstemperatuur, roolheid van die vel en probleme met loop.

Hierdie is almal ernstige newe-effekte. Jy kan moontlik dringende mediese sorg benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Algemene newe-effekte:
- Kneusing, toename in sommige witbloedselle, gebrek aan witbloedselle.
- Swelling van die hande en voete, gewigstoename, hoë cholesterolvlakke in die bloed, hoë suikervlakke in die bloed, hoë vlakke van sekere vette in die bloed, verhoogde eetlus.
- Slapenigheid, duiseligheid, onvermoë om stil te sit, toename in parkinsonsiemiese simptome - soos bewing, stadige bewegeng, aangeplaste spreek of spierstyfheid.
- In die vroeë stadiums van behandeling, kan sommige mense duiselig voel of flou word (met 'n stadige hartempo), veral wanneer hulle opstaan uit 'n lê- of sitposisie. Dit sal gewoonlik vanself verbygaan, maar indien dit nie gebeur nie, vertel jou dokter.
- Hardlywigheid, droë mond
- Gewrigspyn
- Seksuele disfunksie sooe verminderde libido in mans en vrouens of erektiele disfunksie in mans, abnormale ejakulasie.
- Ongewone moegheid of swakheid, koors, swelling.
- **Bejaarde pasiënte met demensie kan ly aan** longontsteking, urinêre inkontinensie, valle, sukkel om te loop.

Minder algemene newe-effekte:
- Lae bloedplaatjietelling wat bloeding of kneusing maklker as normaalweg tot gevolg het.
- Onwillekeurige sametrekking van spiere, onwillekeurige opwaartse afwyking van die oë, gehaueverlies, sleepvoet- of stadige spraak, haklsel, onweerstaanbare drang om die bene te beweeg.
- Neusbloeding.
- Opgeblasenheid en swelling in die bulkarse.
- Verneersiee in die lewer (simptome sluit in verlies aan selfus, gewigsverlies, swelsheid, moegheid, neusbloedings, jeukerige vel, geel vel en oë).
- Uitslag, roolheid van die vel as gevolg van bloototstelling aan die son, haarverlies.
- Pynlike of moeilike urinering, die behoefte om baie keer te urineer, gedurende die dag en nag, onvermoë om die blaas heeltemal of gedeeltelik leeg te maak, meer urlene te lewer as normaal.
- **NEZOLAP** kan neonatale geneesmiddelontrekkingsindroom veroorsaak wat gebeur wanneer babas voor geboorte aan medisyne in die baarmoeder blootgestel word. Babas word dan aangetas of ondergaan geneesmiddelontrekking ná geboorte. Tekens van pasgebore geneesmiddelontrekking sluit in vlekka op die vel, diarree, lastigheid, koors, braking, bewing en stadige ontwikkeling.
- Afwesigheid of afname in maandsiondo, verrandeinge in borste in mans en vrouens, sooi 'n abnormale produksie van borsmelk of abnormale groei.
- Bloedtoets kan verhoogde lewensiesme, verhoogde prolaktien, verhoogde alkaliese fosfatase, hoë kreatienfosfokinase, hoë gamma-glutamieltransferase, hoë urienvaar en verhoogde totale bilirubien toon.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, moet jy asseblief jou dokter of apteker daarvan in kennis stel.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in, wat nie in hierdie inligtingsblad gelys is nie. Jy kan ook newe-effekte aanmeld by 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 jy help om meer inligting oor die veiligheid van **NEZOLAP** te verskaf.

5. Hoe om NEZOLAP te berg

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig.
Bewaar alle medisyne buite bereik van kinders.
Bewaar in die oorspronklike verpakking/houer.
Bewaar die stulpstrook in die karton totdat dit benodig word vir gebruik.
Hou die HDPE houers dig gesluit.
Moet nie in 'n badkamer bare nie.
Moet nie na die vervaldatum wat aangebring is op die stulpstrook / etiket / karton / bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in die riool of nooitasiel (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat NEZOLAP bevat
- Die aktiewe bestanddeel is 2,5 mg, 5 mg en 10 mg olansapien.
- Die ander bestanddele is mikrokristalline sellulose, lae gesubstitueerde hidroksipropielsellulose, kruispovidoon en magnesiumstearaat, bedekkingsmiddel bevat gedeeltelike gehidroliseerde polivinielalkohol, titaandioksied (CI77891), talkpoeier, fesilien (soja) en xantan gom.

Wat NEZOLAP ODT bevat
- Die aktiewe bestanddeel is 5 mg, 10 mg, 15 mg en 20 mg olansapien.
- Die ander bestanddele is aspartaam, kruispovidoon, lae gesubstitueerde hidroksipropielsellulose (L-HPS-LH-11), magnesiumstearaat en mikrokristalline sellulose.

Hoe NEZOLAP lyk en die inhoud van die pak
NEZOLAP 2,5 mg:
Wit- tot naaswitgekleurde, ronde vorm, bikonvekse, filmbedekte tablette, met 'CL' op die een kant gedruk en '39' aan die ander kant gedruk.
NEZOLAP 5 mg:
Wit- tot naaswitgekleurde, ronde vorm, bikonvekse, filmbedekte tablette, met 'CL 40' op die een kant gedruk en onverseer aan die ander kant.
NEZOLAP 10 mg:
Wit- tot naaswitgekleurde, ronde vorm, bikonvekse, filmbedekte tablette, met 'CL 42' op die een kant gedruk en onverseer aan die ander kant.
NEZOLAP ODT 5 mg:
Geel, ronde vorm, bikonvekse, onbedekte tablette, met 'MIL 35" op die een kant gedruk en onverseer aan die ander kant.
NEZOLAP ODT 10 mg:
Geel, ronde vorm, bikonvekse, onbedekte tablette, met 'MIL 36" op die een kant gedruk en onverseer aan die ander kant.
NEZOLAP ODT 15 mg:
Geel, ronde vorm, bikonvekse, onbedekte tablette, met 'MIL 37" op die een kant gedruk en onverseer aan die ander kant.
NEZOLAP ODT 20 mg:
Geel, ronde vorm, bikonvekse, onbedekte tablette, met 'CL 1" op die een kant gedruk en onverseer aan die ander kant.

1) Stulpstrook verpakking:
NEZOLAP en **NEZOLAP** ODT word verpak in koue vorm gelamineerde 25 µ OPA/45 µ aluminiumfoelie/50 µ PVC as die vormgemateriaal en 25 µ gewone aluminiumfoelie/5-ll gem hitte seël laksems as die deurmateriaal, verpak in 'n voorafgedrukte karton.
Verpakkingsgrootte bevat 10, 28 of 30 tabletta.

2) HDPE houer verpakking:
NEZOLAP tablette is verpak in wit ronde 60 ml HDPE houer met 33 mm nekafwerking wat geseël is met 'n 33 mm kinderbestande sluiting met pulp en hitte seël voering en verpak in 'n buitenste karton. Elke HDPE houer bevat 1 sakkie met 1 g silikagel.
NEZOLAP ODT is verpak in wit ronde 40 ml of 60 ml HDPE houer met 33 - 400 mm nekafwerking wat geseël is met 'n 33 mm kinderbestande sluiting met pulp en hitte seël voering en verpak in 'n buitenste karton. Elke HDPE houer bevat 1 sakkie met 1 g silikagel.
Verpakkingsgrootte sluit 28 of 30 tablette in.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemerk nie.

Houer van die Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Rylaan 1, Bassonia Rock, Uitbreiding 12.
Alberton, Suid-Afrika

Hierdie inligtingsblad is laas hersien in:
23 Maart 2021

Registrasienommer:
NEZOLAP 2,5 mg: 47/2.6.5/0284
NEZOLAP 5 mg: 47/2.6.5/0285
NEZOLAP 10 mg: 47/2.6.5/0286
NEZOLAP ODT 5 mg: 48/2.6.5/0343
NEZOLAP ODT 10 mg: 48/2.6.5/0344
NEZOLAP ODT 15 mg: 48/2.6.5/0345
NEZOLAP ODT 20 mg: 48/2.6.5/0346

Vir die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan by https://medeodssaproducts.co.za/ verkry word of deur 011 682 1169 te kontak

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Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Change in description of Olanzapine Tablets from close 4 to open 4.

1. Product: Nezolap (Olanzapine FCT & ODT)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 GSM Bible paper	
7. Machine Layout No.: NA	8. Dimensions: 410(L) x 340(W) mm
9. Design / Style: Booklet	10. Item code No.: PM03920303
11. Artwork has been made: Actual Size	12. Pharma code No.: 33346 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: PM03920302
15. Revision no: 02	AW File name:X:\Olanzapine FCT\SA Private Market\PM\Olanzapine FCT-ODT PI & PIL - PM03920303.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
16/11/23	Vanita Rajool	16/11/23	18/11/23	18/11/23	18/11/23

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

Instructions to Vendor :

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

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03920301	01/09/22	19/05/23
2) Exclude Professional Information & dimensions change.	PM03920302	21/10/23	Not Implementated
3) Change in description of Olanzapine Tablets from close 4 to open 4.	PM03920303		

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