Front Top
340 mm

400 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

ZIPSID 20 mg
Ziprasidone 20 mg
Contains sugar: (17,2 mg lactose monohydrate and 10 mg sucrose)

ZIPSID 40 mg
Ziprasidone 40 mg
Contains sugar: (34,4 mg lactose monohydrate and 20 mg sucrose)

ZIPSID 60 mg
Ziprasidone 60 mg
Contains sugar: (51,6 mg lactose monohydrate and 30 mg sucrose)

ZIPSID 80 mg
Ziprasidone 80 mg
Contains sugar: (68,8 mg lactose monohydrate and 40 mg sucrose)

Read all of this leaflet carefully before you start taking ZIPSID
- 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.
- **ZIPSID** 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 **ZIPSID** is and what it is used for
2. What you need to know before you take **ZIPSID**
3. How to take **ZIPSID**
4. Possible side effects
5. How to store **ZIPSID**
6. Contents of the pack and other information

1. What ZIPSID is and what it is used for

ZIPSID capsules belong to a group of medicines called antipsychotics. **ZIPSID** capsules are used for the treatment of schizophrenia in adults - a mental disorder characterised by the following symptoms: to hear, see and feel things that do not exist, to believe in something not true, to feel unusual suspicions, to be absent and have difficulty in establishing social relationships, nervousness, depression or anxiety.

2. What you need to know before you take ZIPSID

Do not take ZIPSID:
- if you are allergic to ziprasidone or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include rash, itching, swelling in the face or lips, difficulty in breathing.
- if you suffer or have suffered from heart problems or have recently had a heart attack.
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm.

Also refer to the section "Other medicines and **ZIPSID**" below.
- If you are pregnant or breastfeeding
- If you are under the age of 18 years

Warnings and precautions
Take special care with ZIPSID
Talk to your doctor, pharmacist or nurse before taking **ZIPSID**
- if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- if you have liver problems
- if you suffer or have suffered from seizure or epilepsy
- if you are elderly (over 65 years old) and suffer from dementia and are at risk of having a stroke
- if you have a low resting heartrate and/or you know that, you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate
- if you have diabetes

Contact your doctor immediately if you experience any of the following:
- Severe skin reactions such as rash with blisters which could include ulcers in the mouth, skin shedding, fever and target-like spots on the skin that could be symptoms of Stevens-Johnson syndrome. These skin reactions could potentially be life-threatening.
- **ZIPSID** may cause sleepiness, fall in blood pressure when standing up, dizziness and gait disturbances, which may lead to falls. Caution should be taken, particularly if you are an elderly patient or have some debility.

Tell your doctor that you are taking **ZIPSID** before you have a laboratory test (such as blood, urine, liver function, heart rate etc) because it may alter the results of the test.

Use in children and adolescents
The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, ziprasidone should not be used in this age group.

Other medicines and ZIPSID
Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).
Do not take **ZIPSID** if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as:
Class IA and III antidysrhythmics, arsenic trioxide, halofantrine, levomethadyl acetate, mesoridazine, thioridazine, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, dolasetron mesilate, mefloquine, sertindole or cisapride. These medicines affect the heart rhythm by prolonging the QT interval. If you have any further questions about this you should speak to your doctor.
Please tell your doctor or pharmacist if you are taking or have recently taken medicines for the treatment of:
- bacterial infections; these medicines are known as antibiotics; e.g. macrolide antibiotics or rifampicin;
- mood swings (ranging from depressive mood to euphoria), agitation and irritation; these are known as mood stabilising medicines e.g. lithium, carbamazepine, valproate;
- depression, including certain serotonergic medicines e.g. SSRI's such as fluoxetine, paroxetine, sertraline; or herbal medicines or natural remedies containing St John's Wort;
- epilepsy e.g. phenytoin, phenobarbital, carbamazepine, ethosuximide;
- Parkinson's disease e.g. levodopa, bromocriptine, ropinirol, pramipexole;
- or if you are taking or have recently taken the following medicines: verapamil, quinidine, itraconazole or ritonavir.

Also refer to the section "Do not take **ZIPSID**" above.

ZIPSID with food and drink:
ZIPSID MUST BE TAKEN DURING A MAIN MEAL.

You should not drink alcohol during treatment with **ZIPSID**, as this may increase the risk of side effects.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ZIPSID**.
Do not take **ZIPSID** if you are pregnant. Inform your doctor immediately if you are pregnant or intend to become pregnant.
Do not breastfeed if you are taking **ZIPSID**.
If you are a woman of childbearing age, make sure you use effective contraception while on treatment with **ZIPSID**.

Driving and using machines
Taking **ZIPSID** may make you feel drowsy. If you experience this symptom, you should not drive or use tools or machinery until the drowsiness disappears.
It is not always possible to predict to what extent **ZIPSID** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **ZIPSID** affects you.

ZIPSID contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

ZIPSID
20/40/60/80 mg
PM03935502

3. How to take ZIPSID

Do not share medicines prescribed for you with any other person.
Always take **ZIPSID** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
Take the number of capsules as your doctor has instructed you.
The capsules should be swallowed whole, not chewed and must be taken with meals. It is important not to chew the capsules as it may affect the extent to which the medicine is absorbed by the gut.
ZIPSID should be taken twice daily, one capsule in the morning during a full 'breakfast' and one in the evening during the 'evening meal'. You should take this medicine at the same time every day.
The usual dose is 40 mg twice daily. Your doctor will adjust your dose based on your response. The maximum dose is 80 mg twice daily.
Elderly (over 65 years old)
If you are elderly, your doctor will decide the suitable dose for you. Doses in those over 65 are sometimes lower than those used in younger people. Your doctor will advise you what the right dose is for you.
Patients with liver problems
If you have liver problems you may need to take a lower dose of **ZIPSID**. Your doctor will work out the correct dose for you.
Continue taking **ZIPSID** until your doctor tells you to stop.
If you have the impression that the effect of **ZIPSID** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ZIPSID than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
If you have taken too many **ZIPSID**, you may experience drowsiness, shaking, fits and involuntary movements of the head and neck.

If you forget to take ZIPSID
It is important to take your **ZIPSID** capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking ZIPSID
If **ZIPSID** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **ZIPSID** for as long as your doctor has prescribed.

4. Possible side effects

ZIPSID can have side effects.
If any of the following happens, stop taking **ZIPSID** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling in the face, lips, tongue or throat
- Swallowing or breathing problems
- Anettle rash

These are all very serious side effects. If you have them, you may have had a serious reaction to **ZIPSID**. 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:
- Involuntary/unusual movements, especially in your face or tongue.
- Fast or irregular heartbeat, dizziness on standing up which may indicate abnormal functioning of the heart. These could be symptoms of a condition known as postural hypotension.
- Skin reactions, in particular rash, fever and swollen lymph nodes which could be symptoms of a condition called drug reaction with eosinophilia and systemic symptoms (DRESS). These reactions could be potentially life-threatening.
- Fever, faster breathing, sweating, muscle stiffness, shaking, difficulty swallowing and reduced consciousness. These could be symptoms of a condition known as neuroleptic malignant syndrome.
- Confusion, agitation, high temperature, sweating, lack of muscle co-ordination, muscle twitching. These could be symptoms of a condition known as serotonin syndrome.
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.
- 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.
- Persistent abnormal and painful erection of the penis.

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

You may also experience any of the following side effects listed below. These potential side effects generally are mild to moderate and may resolve with time. However, if the side effect is severe or persistent, you should contact your doctor.
Frequent side effects:
- Runny nose
- High mood energy, strange thinking patterns and hyperactivity, feeling agitated or anxious
- Restlessness
- Abnormalities of movement including involuntary movements, muscular rigidity, slowness of movements
- Dizziness
- Sedation
- Difficulty sleeping
- Sleepiness or excessive daytime sleepiness
- Headache
- Blurred or impaired vision
- High blood pressure
- Constipation, diarrhoea, nausea, vomiting and indigestion, dry mouth, increased salivation
- Rash
- Male sexual problems
- Fever, pain
- Exhaustion
- General feeling of illness
- Feeling hot
- Weight loss or gain

Less frequent side effects:
- Decrease or increase in white blood cells (in blood test)
- High levels of prolactin in the blood (determined by blood test)
- Increased appetite
- Decrease in calcium levels in the blood (determined by blood test)
- Panic attack
- Feeling nervous or depressed
- Decreased sexual desire
- Loss of consciousness
- Difficulty in controlling movements/involuntary movements
- Restless legs
- Throat tightness, nightmares
- Seizures, involuntary eyes movements into a fixed position, clumsiness, speech disorder, numbness, pins and needles sensation, reduced ability to concentrate, drooling
- Slowed thinking, lack of emotions
- Facial droop
- Paralysis
- Partial or complete loss of vision in one eye, itchy eyes
- Difficulty speaking, hiccups
- Palpitation, breathlessness
- Sensitivity to light, dry eyes
- buzzing in the ears, ear pain
- Vertigo
- Sore throat, wind, stomach discomfort
- Itchy skin rash, acne, skin irritations, hair loss
- Patches of raised and inflamed red skin covered by a white scale known as psoriasis
- Muscle cramp, stiff or swollen joints
- Thirst, chest discomfort, abnormal walk
- Unusual position of head
- Inability to open mouth
- Acid reflux, stomach pain
- Loose stools
- Urinary incontinence, pain or difficulty urinating, difficulty emptying bladder
- Abnormal breast milk production
- Breast enlargement in men
- Absence of menstruation
- Reduced orgasm
- Abnormal heart or blood test results
- Abnormal liver function test results
- General weakness and tiredness
- Drug withdrawal syndrome in newborn babies

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Not all the side effects reported for **ZIPSID** are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking **ZIPSID**, please consult your healthcare provider for advice.

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 **ZIPSID**.

5. How to store ZIPSID

Store at or below 25 °C (room temperature). Protect from light.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Keep the HDPE containers 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 ZIPSID contains
The active ingredient is ziprasidone hydrochloride monohydrate.
The other ingredients are:
polyethylene glycol 6000, lactose monohydrate, sodium starch glycollate, ammonium chloride, sucrose and sodium lauryl sulphate.
Hard gelatin capsule for **ZIPSID 20 mg, ZIPSID 40 mg** and **ZIPSID 80 mg** contain FD & C blue 2 (CI no. 73015), titanium dioxide, gelatin and sodium lauryl sulfate and black edible printing ink.
Hard gelatin capsule for **ZIPSID 60 mg** contains titanium dioxide, gelatin and sodium lauryl sulfate and black edible printing ink.
Contains sugar: lactose monohydrate and sucrose.
ZIPSID 20 mg contains 17,2 mg lactose monohydrate and 10 mg sucrose per capsule.
ZIPSID 40 mg contains 34,4 mg lactose monohydrate and 20 mg sucrose per capsule.
ZIPSID 60 mg contains 51,6 mg lactose monohydrate and 30 mg sucrose per capsule.
ZIPSID 80 mg contains 68.8 mg lactose monohydrate and 40 mg sucrose per capsule.

What ZIPSID looks like and contents of the pack
ZIPSID 20 mg: Blue/White, size 4, hard gelatin capsules imprinted in Black ink with "CL62" on cap and "20 mg" on the body containing pale pink colored powder.

ZIPSID 40 mg: Blue/Blue, size 2, hard gelatin capsules imprinted in Black ink with "CL63" on cap and "40 mg" on the body containing pale pink colored powder.

ZIPSID 60 mg: White/White, size 1, hard gelatin capsules imprinted in Black ink with "CL64" on cap and "60 mg" on the body containing pale pink colored powder.

ZIPSID 80 mg: Blue/White, size 0, hard gelatin capsules imprinted in Black ink with "CL65" on cap and "80 mg" on the body containing pale pink colored powder.

Blister Pack:
Capsules are packed in cold form laminate OPA /Alu foil /PVC as forming material, and plain aluminum foil/heat seal lacquer as lidding material.
Pack size 14's, 20's, 30's, 50's, 56's, 60's or 100's capsules.

HDPE Container Pack:
Capsules are packed in round, white HDPE container with screw neck with white child-resistant polypropylene or continuous thread closure with pulp and heat seal liner.
Pack size 60's, 100's or 300's capsules
Not all pack sizes are marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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Registration number
ZIPSID 20 mg: 48/2.6.5/0710
ZIPSID 40 mg: 48/2.6.5/0711
ZIPSID 60 mg: 48/2.6.5/0712
ZIPSID 80 mg: 48/2.6.5/0713

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

Back Top

340 mm

400 mm

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

ZIPSID 20 mg
Ziprasidoon 20 mg
Bevat suiker: (17,2 mg laktosemonohidraat en 10 mg sukrose)

ZIPSID 40 mg
Ziprasidoon 40 mg
Bevat suiker: (34,4 mg laktosemonohidraat en 20 mg sukrose)

ZIPSID 60 mg
Ziprasidoon 60 mg
Bevat suiker: (51,6 mg laktosemonohidraat en 30 mg sukrose)

ZIPSID 80 mg
Ziprasidoon 80 mg
Bevat suiker: (68,8 mg laktosemonohidraat en 40 mg sukrose)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy ZIPSID begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **ZIPSID** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

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

1. Wat ZIPSID is en waarvoor dit gebruik word

ZIPSID kapsules behoort aan 'n groep medisyne wat antipsigotiese middels genoem word. **ZIPSID** kapsules word gebruik vir die behandeling van skisofrenie in volwassenes - 'n geestesversteuring wat gekenmerk word deur die volgende simptome: om dinge te hoor, te sien en te voel wat nie bestaan nie, om te glo in iets wat nie waar is nie, om ongewone vermoedens te hê, om afwesig te wees en probleme te hê met die vestiging van sosiale verhoudings, senuweeagtigheid, depressie of angs.

2. Wat jy behoort te weet voordat jy ZIPSID neem

Moet nie ZIPSID neem nie:
- indien jy allergies vir ziprasidoon of enige van die ander bestanddele van hierdie medisyne is (gelys in afdeling 6).

Tekens van 'n allergiese reaksie sluit in uitslag, jeuk, swelling in die gesig of lippe, moeilike asemhaling.
- indien jy ly of gely het aan hartprobleme of onlangs 'n hartaanval gehad het.
- indien jy medisyne neem vir hartritme probleme of wat die hart se ritme kan beïnvloed.

Verwys ook na die afdeling "Ander medisyne en **ZIPSID**" hieronder.
- Indien jy swanger is of borsvoed
- Indien jy onder die ouderdom van 18 jaar is

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met ZIPSID
Praat met jou dokter, apteker of verpleegkundige voordat jy **ZIPSID** neem
- indien jy of iemand anders in jou familie 'n geskiedenis van bloedklonte het, aangesien medisyne soos hierdie geassosieer is met die vorming van bloedklonte
- indien jy lewerprobleme het
- indien jy aan stuipe of epilepsie ly of gely het
- indien jy bejaard is (bo 65 jaar oud) en aan dimensie ly en die risiko loop om 'n beroerte te kry
- indien jy 'n lae rustende harttempo het en/of jy weet dat jy soutuitputting kan hê as gevolg van langdurige erge diaree en braking (om siek te wees) of die gebruik van diuretika (water tablette)
- indien jy 'n vinnige of onreëlmatige hartklop, floute, ineenstorting of duiseligheid ervaar wanneer jy opstaan, wat kan dui op abnormale funksionering van die harttempo
- indien jy diabetes het

Kontak onmiddellik jou dokter indien jy enige van die volgende ervaar:
- Ernstige velreaksies soos uitslag met blase wat sere in die mond, vel verlies, koors en teikenagtige kolle op die vel kan insluit wat simptome van Stevens-Johnson-sindroom kan wees. Hierdie velreaksies kan moontlik lewensgevaarlik wees.
- **ZIPSID** kan slaperigheid, deling in bloeddruk wanneer opstaan, duiseligheid en stap stoomiase veroorsaak, wat kan lei tot val. Omsigtigheid moet geneem word, veral as jy 'n bejaarde pasiënt is of 'n mate van swakheid het.

Vertel jou dokter dat jy **ZIPSID** neem voordat jy 'n laboratoriumtoets doen (soos bloed, urine, lewerfunksie, harttempo, ens.) want dit kan die resultate van die toets verander.

Gebruik in kinders en adolessente
Die veiligheid en doeltreffendheid in kinders en adolessente (onder 18 jarige ouderdom) is nie vasgestel nie en daarom moet ziprasidoon nie in hierdie ouderdomsgroep gebruik word nie.

Ander medisyne en ZIPSID
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Moet nie **ZIPSID** neem as jy medisyne neem vir hartritme probleme of medisyne wat die hart se ritme kan beïnvloed nie, soos:
Klas IA en III anti-ritmiese middels, arseentrioksied, halofantrien, levomeladilaseetaat, mesoridasien, floridasien, pimosied, sparfloksasien, gatifloksasien, moksifloksasien, dolasetronmesilaat, mefloklen, sertindool of sisapried. Hierdie medisyne affekteer die hartritme deur die QT-interval te verleng. As jy enige verdere vrae hieroor het, moet jy met jou dokter praat.
Vertel asseblief jou dokter of apteker as jy medisyne neem of onlangs geneem het vir die behandeling van:
- bakteriële infeksies; hierdie medisyne staan bekend as antibiotika; bv. makrolied antibiotika of rifampisien;.
- gemoedskommelings (wat wissel van depressiewe bui tot euforie), agitasie en irritasie; dit staan bekend as bui stabiliserende medisyne bv. litium, karbamasepien, valproaat;
- depressie, insluitend sekere serotonergiese medisyne, bv. SSHI's soos fluoksetien, paroksetien, sertralien; of kruiemedisyne of natuurlike middels wat St Johannes Kruid bevat;
- epilepsie bv. fenitoïen, fenobarbitoon, karbamasepien, etosuksimied;
- Parkinson se siekte bv. levodopa, bromokriptien, ropinirol, pramipeksool;
- of as jy die volgende medisyne neem of onlangs geneem het: verapamil, kinidien, itrakonasool of ritonavir.

Verwys ook na die afdeling "Moet nie **ZIPSID** neem nie" hierbo.

ZIPSID met voedsel en vloeistof:
ZIPSID MOET TYDENS 'N HOOFMAALTYD GENEEM WORD.

Jy moet nie alkohol drink tydens behandeling met **ZIPSID** nie, aangesien dit die risiko van newe-effekte kan verhoog.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, dink dat jy dalk swanger is, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **ZIPSID** neem.
Moet nie **ZIPSID** neem indien jy swanger is nie. Stel onmiddellik jou dokter in kennis as jy swanger is of van plan is om swanger te word.
Moet nie borsvoed as jy **ZIPSID** gebruik nie.
Indien jy 'n vrou van kinderbarende ouderdom is, maak seker dat jy effektiewe voorbehoedmiddels gebruik terwyl jy op **ZIPSID** behandeling is.

Bestuur en gebruik van masjinerie
Die neem van **ZIPSID** kan jou lomerig laat voel. Indien jy hierdie simptoom ervaar, moet jy nie bestuur of gereedskap of masjinerie gebruik totdat die lomerigheid verdwyn nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **ZIPSID** met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie by bogenoemde aktiwiteite betrokke raak voordat jy bewus is van die mate waarin **ZIPSID** jou affekteer nie.

ZIPSID bevat laktose.
Indien jy deur jou dokter gesê is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie medisyne neem.

3. Hoe om ZIPSID te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **ZIPSID** presies soos jou dokter vir jou voorgeskryf het. Bevestig met jou dokter of apteker as jy nie seker is nie.
Neem die aantal kapsules soos jou dokter jou beveel het.
Die kapsules moet heel ingesluk word, nie gekou word nie, en moet saam met etes geneem word. Dit is belangrik om nie die kapsules te kou nie, aangesien dit die mate waarin die medisyne deur die ingewande geabsorbeer word, kan beïnvloed.
ZIPSID moet twee keer per dag geneem word, een kapsule in die oggend tydens 'n volledige 'ontbyt' en een in die aand tydens die 'aandete'. Jy moet hierdie medisyne elke dag op dieselfde tyd neem.
Die gewone dosis is 40 mg twee keer per dag. Jou dokter sal jou dosis aanpas op grond van jou reaksie. Die maksimum dosis is 80 mg twee keer per dag.
Bejaardes (bo 65 jaar oud)
Indien jy bejaard is, sal jou dokter oor die geskikte dosis vir jou besluit. Doserings in diegene ouer as 65 is soms laer as dié wat in jonger mense gebruik word. Jou dokter sal jou adviseer wat die regte dosering vir jou is.
Pasiënte met lewerprobleme
Indien jy lewerprobleme het, sal jy dalk 'n laer dosis **ZIPSID** moet neem. Jou dokter sal die korrekte dosis vir jou uitwerk.
Gaan voort om **ZIPSID** te neem totdat jou dokter vir jou sê om op te hou.
Indien jy die indruk het dat die effek van **ZIPSID** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer ZIPSID neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Indien jy te veel **ZIPSID** geneem het, kan jy lomerigheid, bewing, aanvalle en onwillekeurige bewegings van die kop en nek ervaar.

Indien jy vergeet om ZIPSID te neem
Dit is belangrik om jou **ZIPSID** kapsules gereeld op dieselfde tyd elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosering. Moet nie twee dosisse gelyktydig neem, om op te maak vir 'n vergete dosis nie.

Indien jy ophou om ZIPSID te neem
Indien **ZIPSID** vroeër gestop word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **ZIPSID** vir so lank as wat jou dokter voorgeskryf het.

4. Moontlike newe-effekte

ZIPSID kan newe-effekte hê.
Indien enige van die volgende gebeur, hou op om **ZIPSID** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Swelling in die gesig, lippe, tong of keel
- Probleme om te sluk of asem te haal
- 'n Brandnetel uitslag

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **ZIPSID** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Onwillekeurige/ongewone bewegings, veral in jou gesig of tong.
- Vinnige of onreëlmatige hartklop, duiseligheid wanneer jy opstaan, wat kan dui op abnormale funksionering van die hart. Hierdie kan simptome wees van 'n toestand bekend as posturale hipotensie.
- Velreaksies, in die besonder uitslag, koors en geswelde limfknope wat simptome kan wees van 'n toestand wat geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS) genoem word. Hierdie reaksies kan potensieel lewensgevaarlik wees.
- Koors, vinniger asemhaling, sweet, spierstyfheid, bewing, sukkel om te sluk en verminderde bewussyn. Hierdie kan simptome wees van 'n toestand bekend as neuroleptiese maligne sindroom.
- Verwarring, rusteloosheid, hoë temperatuur, sweet, gebrek aan spierkoördinasie, spierrekkings. Hierdie kan simptome wees van 'n toestand bekend as serotoniensindroom.
- Vinnige, onreëlmatige hartklop, floute wat simptome kan wees van 'n lewensgevaarlike toestand bekend as *Torsades de Pointes*.
- Bloedklonte in die arm veral in die bene (simptome sluit in swelling, pyn en rooiheid in die been), wat deur bloedvate na die longe kan beweeg en borskaspyn en moeilike asemhaling veroorsaak.
- Aanhoudende abnormale en pynlike verstywing van die penis.

Hierdie is alles ernstige newe-effekte. Jy benodig dalk dringende mediese aandag.

Jy kan ook enige van die volgende newe-effekte ervaar wat hieronder gelys word. Hierdie potensiële newe-effekte is oor die algemeen lig tot matig en kan mettertyd verdwyn. As die newe-effek egter ernstig of aanhoudend is, moet jy jou dokter kontak.
Gereelde newe-effekte:
- Loopneus
- Hoë bui energie, vreemde denkpatrone en hiperaktiwiteit, veel opgewonde of angstig
- Rusteloosheid
- Abnormaliteite van beweging insluitend onwillekeurige bewegings, spiertigiditeit, traagheid van bewegings
- Duiseligheid
- Sedasie
- Sukkel om te slaap
- Slaperigheid of oormatige slaperigheid gedurende die dag
- Hoofpyn
- Dowwe of verswakte visie
- Hoë bloeddruk
- Hardlywigheid, diaree, naarheid, braking en swak spysvertering, droë mond, verhoogde speekselafskeiding
- Uitslag
- Manlike seksuele probleme
- Koors, pyn
- Uitputting
- Algemene gevoel van siekte
- Veel warm
- Gewigsverlies of -toename

Minder gereelde newe-effekte:
- Afname of toename in witbloedselle (in bloedtoets)
- Hoë vlakke van prolaktien in die bloed (vasgestel deur bloedtoets)
- Verhoogde eosinofiele
- Afname in kalsiumvlakke in die bloed (vasgestel deur bloedtoets)
- Paniek aanval
- Senuweeagtig of depressief voel
- Verminderde seksuele begeerte
- Verlies van bewussyn
- Moeilik om bewegings te beheer/onwillekeurige bewegings
- Rustelose bene
- Toegetrekte keel, nagmerries
- Aanvalle, onwillekeurige bewegings van die oë in 'n vaste posisie, lompheid, spraak versteuring, gevoelloosheid, spalde- en naalde sensasie, verminderde vermoë om te konsentreer, kwyl
- Vertraagde denke, gebrek aan emosies
- Hang van gesig
- Verlamming
- Gedeeltelike of volledige verlies van visie in een oog, jeukerige oë
- Moeilik praat, hik
- Hartkloppling, kortasem
- Sensitiwiteit vir ligte, droë oë
- gesuis in die ore, oorpyn
- Vertigo
- Seer keel, wind, maag ongemak
- Jeukerige veluitslag, aknee, velirritasies, haarverlies
- Plekke van opgehewe en ontsteekte rooi vel bedek deur 'n wit skub bekend as psoriase
- Spierkrampe, stywe of geswelde gewrigte
- Dors, borskas ongemak, abnormale stap
- Ongewone posisie van kop
- Onvermoë om mond oop te maak
- Suur terugvloei, maagpyn
- Los stoelgange
- Urinêre inkontinensie, pyn of probleme om te urineer, probleme om blaas leeg te maak
- Abnormale borsmelkproduksie
- Borsvergroting in mans
- Afwesigheid van menstruasie
- Verminderde orgasme
- Abnormale hart- of bloedtoetsresultate
- Abnormale lewerfunksietoets resultate
- Algemene swakheid en moegheid
- Geneesmiddelonttrekkingsindroom in pasgebore babas

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.
Nie al die newe-effekte wat vir **ZIPSID** aangemeld is, is in hierdie inligtingstuk ingesluit nie.
Indien jou algemene gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl jy **ZIPSID** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

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 inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van 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 beskikbaar te stel aangaande die veiligheid van **ZIPSID**.

5. Hoe om ZIPSID te bewaar

Bewaar by of benede 25 °C (kamertemperatuur). Beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS.
Berg in die oorspronklike verpakking/houer.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houers dig toe.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat aangebring is op die stulpstrook/etiket/karton/bottel nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat ZIPSID bevat
Die aktiewe bestanddeel is ziprasidoonhidrochloried monohidraat.
Die ander bestanddele is:
poliëtileenglikol 6 000, laktosemonohidraat, natriumstyselglikolaat, ammoniumchloried, sukrose en natriumlaurielsulfaat.
Harde gelatienkapsule vir **ZIPSID 20 mg, ZIPSID 40 mg** en **ZIPSID 80 mg** bevat FD & C blou 2 (CI no. 73015), titaandioksied, gelatien en natriumlaurielsulfaat en swart eetbare drukink.
Harde gelatienkapsule vir **ZIPSID 60 mg** bevat titaandioksied, gelatien en natriumlaurielsulfaat en swart eetbare drukink.
Bevat suiker: laktosemonohidraat en sukrose.
ZIPSID 20 mg bevat 17,2 mg laktosemonohidraat en 10 mg sukrose per kapsule.
ZIPSID 40 mg bevat 34,4 mg laktosemonohidraat en 20 mg sukrose per kapsule.
ZIPSID 60 mg bevat 51,6 mg laktosemonohidraat en 30 mg sukrose per kapsule.
ZIPSID 80 mg bevat 68,8 mg laktosemonohidraat en 40 mg sukrose per kapsule.

Hoe ZIPSID lyk en inhoud van die pak
ZIPSID 20 mg: Blou/Wit, grootte 4, harde gelatienkapsules gedruk in swart ink met "CL62" op die doppie en "20 mg" op die lyfie wat ligpienk gekleurde poeier bevat.

ZIPSID 40 mg: Blou/Blou, grootte 2, harde gelatienkapsules gedruk in swart ink met "CL63" op die doppie en "40 mg" op die lyfie wat ligpienk gekleurde poeier bevat.

ZIPSID 60 mg: Wit/Wit, grootte 1, harde gelatienkapsules gedruk in swart ink met "CL64" op die doppie en "60 mg" op die lyfie wat ligpienk gekleurde poeier bevat.

ZIPSID 80 mg: Blou/Wit, grootte 0, harde gelatienkapsules gedruk in swart ink met "CL65" op die doppie en "80 mg" op die lyfie wat ligpienk gekleurde poeier bevat.

Stulpstrook verpakking:
Kapsules word verpak in koue vorm gelamineerde OPA / Alu foelie / PVC as vormingsmateriaal, en gewone aluminiumfoelie/hittesëllak as dekmateriaal.
Verpakkingsgroottes 14's, 20's, 30's 50's, 56's 60's of 100's kapsules.

HDPE houer verpakking:
Kapsules word verpak in ronde, wit HDPE houer met skroefnek met wit kinderbestande polipropileen of deurlopende draadsluiting met pulp en hittesëlvoering.
Verpakkingsgroottes 60's, 100's, 300's kapsules
Nie alle verpakkingsgroottes word bemark nie.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was laas hersien in
27 July 2023

Registrasienommer
ZIPSID 20 mg: 48/2.6.5/0710
ZIPSID 40 mg: 48/2.6.5/0711
ZIPSID 60 mg: 48/2.6.5/0712
ZIPSID 80 mg: 48/2.6.5/0713

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

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclusion of PI & Dimension change.

1. Product: ZIPSID 20/40/60/80 mg (Ziprasidone Capsules 20/40/60/80 mg)	
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: 340 (L) x 400 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM03935502
11. Artwork has been made: Actual Size	12. Pharma code No.: 33287 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: PM03935501
15. Revision no: 01	16. A/W File name:X:\Ziprasidone\SA Private Market\02\Ziprasidone PI & PIL - PM03935502.cdr
Approved By:	17. Location: Daman

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
22/11/2023	Vanita Rajool	22/11/23	22/11/23	22/11/23.	24/11/23

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	PM03935501	18/08/22	12/05/2023
2) Exclusion of PI & Dimension change.	PM03935502		