Front Side

335 mm

310 mm

Grain Direction

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PEXSON 0,375 XR (tablet)
Contains Sugar (Mannitol 12,025 mg)
PEXSON 0,75 XR (tablet)
Contains Sugar (Mannitol 11,650 mg)
PEXSON 1,5 XR (tablet)
Contains Sugar (Mannitol 10,900 mg)
PEXSON 3,0 XR (tablet)
Contains Sugar (Mannitol 9,400 mg)
PEXSON 4,5 XR (tablet)
Contains Sugar (Mannitol 14,100 mg)
Pramipexole

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

1. What PEXSON XR is and what it is used for

PEXSON XR contains the active substance pramipexole and belongs to a group of medicines known as dopamine agonists, which stimulate dopamine receptors in the brain. Stimulation of the dopamine receptors triggers nerve impulses in the brain that help to control body movements.

PEXSON XR is used to treat the symptoms of primary Parkinson's disease in adults. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease).

2. What you need to know before you take PEXSON XR

Do not take PEXSON XR:
- If you are allergic (hypersensitive) to pramipexole or any of the other ingredients of this medicine, (listed in section 6 below).
- If you are under the age of 18.
- If you have moderate to severe kidney problems.

PEXSON XR
0.375/0.75/1.5/3.0/4.5
PM04342086

Warnings and precautions
Talk to your doctor before taking **PEXSON XR** if you have (or have had) or develop any medical conditions or symptoms, especially any of the following:
- Kidney disease
- Hallucinations (seeing, hearing or feeling things that are not there). Most hallucinations are visual.
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs). If you have advanced Parkinson's disease and are also taking levodopa, you might develop dyskinesia during the uptitration of **PEXSON XR.**
- Dystonia (inability of keeping your body and neck straight and upright (axial dystonia)). In particular, you may experience forward flexion of the head and neck (also called antecollis), forward bending of the lower back (also called camptocormia) or sidewards bending of the back (also called pleurothotonus or Pisa Syndrome).
- Sleepiness and episodes of suddenly falling asleep.
- Psychosis (e.g. comparable with symptoms of schizophrenia)
- Vision impairment. You should have regular eye examinations during treatment with **PEXSON XR.**
- Severe heart or blood vessels disease. You will need to have your blood pressure checked regularly, especially at the beginning of treatment. This is to avoid postural hypotension (a fall in blood pressure on standing up).

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.
Tell your doctor if you or your family/carer notices that you are developing mania (agitation, feeling elated or over-excited) or delirium (decreased awareness, confusion or loss of reality). Your doctor may need to adjust or stop your dose.
Tell your doctor if you or your family/caregiver notice that you are developing addiction-like symptoms resulting in a strong craving for high doses of **PEXSON XR** and other medicines that are used to treat Parkinson's disease (known as dopamine dysregulation syndrome).

Use in children and adolescents
The use of **PEXSON XR** in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and PEXSON XR
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Take care if you are taking the following medicines:
- cimetidine (to treat excess stomach acid and stomach ulcers)
- amantadine (which can be used to treat Parkinson's disease)
- mexiletine (to treat irregular heartbeats, a condition known as ventricular dysrhythmia)
- zidovudine (which can be used to treat the acquired immune deficiency syndrome (AIDS), a disease of the human immune system)
- cisplatin (to treat various types of cancers)
- quinine (which can be used for the prevention of painful night-time leg cramps and for the treatment of a type of malaria known as falciparum malaria (malignant malaria))
- procainamide (to treat irregular heart beat)
- If you are taking levodopa, the dose of levodopa is recommended to be reduced when you start treatment with **PEXSON XR**.
- You should avoid taking **PEXSON XR** together with antipsychotic medicines (used for mood or mental illness)

PEXSON XR with alcohol :
Drinking alcohol may worsen the drowsiness caused by **PEXSON XR.**

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 healthcare professional for advice before taking **PEXSON XR**.

Do not take **PEXSON XR** if you are pregnant, are considering becoming pregnant or are breastfeeding.

Driving and using machines
PEXSON XR can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.
PEXSON XR has been associated with sleepiness and episodes of suddenly falling asleep, particularly in patients with Parkinson's disease. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

3. How to take PEXSON XR

Do not share medicines prescribed for you with any other person.

Always take **PEXSON XR** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 0,375 mg per day and then increased every 7 days, up to a maximum dose of 4,5 mg per day if needed.
PEXSON XR must be taken orally only once a day and swallowed whole with water.

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

If you take more PEXSON XR 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 forget to take PEXSON XR
It is important to take your **PEXSON XR** 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 PEXSON XR
If **PEXSON XR** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **PEXSON XR** for as long as your doctor has prescribed.

4. Possible side effects

PEXSON can have side effects**.**
Not all side effects reported for **PEXSON XR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PEXSON XR**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking PEXSON XR and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing and breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **PEXSON XR**. 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:
- Fever, chest pain.

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

Tell your doctor if you notice any of the following:
Frequent
- Sleeplessness (insomnia)
- Hallucinations (seeing, hearing or feeling things that are not there)
- Abnormal dreams
- Urge to behave in an unusual way
- Confusion
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Sleepiness
- Dizziness
- Headache
- Hypotension (low blood pressure)
- Nausea (sickness)
- Vomiting (being sick)
- Constipation
- Tiredness (fatigue)
- Excess of fluid, usually in the legs (peripheral oedema)
- Weight loss including decreased appetite

Less frequent:
- Pneumonia (infection of the lungs)
- Inappropriate antidiuretic hormone secretion
- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
- Strong impulse to gamble excessively despite serious personal or family consequences.
- Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
- Uncontrollable excessive shopping or spending
- Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)
- Delirium (decreased awareness, confusion, loss of reality)
- Paranoia (e.g. excessive fear for one's own well-being)
- Delusion
- Restlessness
- Excessive daytime sleepiness and suddenly falling asleep
- Amnesia (memory disturbance)
- Hyperkinesia (increased movements and inability to keep still)
- Fainting
- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)
- Dyspnoea (difficulties to breathe)
- Hiccups
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Weight increase

Frequency unknown
- Visual impairment

After stopping or reducing your **PEXSON XR** treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **PEXSON XR.**

5. How to store PEXSON XR

Store at or below 30°C for blister pack and Store at or below 25°C for container pack.
Protect from moisture.
Do not store in a refrigerator.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Keep the blisters in the carton until required for use.
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 PEXSON XR contains
The active ingredient is pramipexole.
Contains Sugar - Mannitol
The other ingredients are:
Hypromellose
Pregelatinized starch
Carbomer homopolymer
Colloidal silicon dioxide
Magnesium stearate

What PEXSON XR looks like and contents of the pack
PEXSON 0,375 XR: White coloured, circular, flat, beveled edged, uncoated tablet debossed 'ER 1' on one side of the tablet and '0,375' on other side.
PEXSON 0,75 XR: White coloured, circular, flat, beveled edged, uncoated tablet debossed 'ER 2' on one side of the tablet and '0,75' on other side.
PEXSON 1,5 XR: White coloured, oval shaped, biconvex, uncoated tablet debossed 'ER 3' on one side of the tablet and '1,5' on other side.
PEXSON 3 XR: White coloured, oval shaped, biconvex, uncoated tablet debossed 'ER 5' on one side of the tablet and '3,0' on other side.
PEXSON 4,5 XR: White coloured, oval shaped, biconvex, uncoated tablet debossed 'ER 7' on one side of the tablet and '4,5' on other side

Contents of the pack:
Tablets are packed in a round white 60 HDPE container with a silica gel sachet and closed with a white child resistant closure packed in an outer carton. Pack sizes include 28's, 30's tablets.
Tablets are packed in aluminium foil laminated on one side and laminated to PVC on the other side. Pack sizes include 28's tablets or 30's tablets.
Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
GROUND FLOOR, BLOCK 1,
BASSONIA ESTATE OFFICE PARK (EAST),
1 CUSSONIA DRIVE,
BASSONIA ROCK EXT 12
ALBERTON
GAUTENG

This leaflet was last revised in
25/11/2025

Registration numbers
PEXSON 0,375 XR: 58/5.4.1/0016
PEXSON 0,75 XR: 58/5.4.1/0017
PEXSON 1,5 XR: 58/5.4.1/0018
PEXSON 3,0 XR: 58/5.4.1/0019
PEXSON 4,5 XR: 58/5.4.1/0020

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

Back Side

335 mm

310 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

PEXSON 0,375 XR (tablet)
Bevat suiker (Mannitol 12,025 mg)
PEXSON 0,75 XR (tablet)
Bevat suiker (Mannitol 11,650 mg)
PEXSON 1,5 XR (tablet)
Bevat suiker (Mannitol 10,900 mg)
PEXSON 3,0 XR (tablet)
Bevat suiker (Mannitol 9,400 mg)
PEXSON 4,5 XR (tablet)
Bevat suiker (Mannitol 14,100 mg)
Pramipeksool

Lees hierdie hele inligtingstuk aandagtig deur voordat jy PEXSON XR begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **PEXSON XR** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit kan skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

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

1. Wat PEXSON XR is en waarvoor dit gebruik word

PEXSON XR bevat die aktiewe bestanddeel pramipeksool en behoort tot 'n groep van medisyne wat bekend staan as dopamien agoniste, wat dopamienreseptore in die brein stimuleer. Stimulasie van die dopamienreseptore veroorsaak senuwee-impulse in die brein wat help om liggaamsbewegings te beheer.

PEXSON XR word gebruik om die simptome van primêre Parkinson se siekte in volwassenes te behandel. Dit kan alleen, of in kombinasie met levodopa ('n ander medisyne vir Parkinson se siekte) gebruik word.

2. Wat jy behoort te weet voordat jy PEXSON XR neem

Moet nie PEXSON XR neem nie:
- Indien jy allergies (hipersensitief) is vir pramipeksool of enige van die ander bestanddele van hierdie medisyne, (gelys in afdeling 6 hieronder).
- Indien jy jonger as 18 jarige ouderdom is.
- Indien jy matige tot ernstige nierprobleme het.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy **PEXSON XR** neem indien jy enige mediese toestande of simptome het (of gehad het) of ontwikkel, veral enige van die volgende:
- Niersiekte
- Hallusinasies (sien, hoor of voel dinge wat nie daar is nie). Die meeste hallusinasies is visueel.
- Diskinesie (bv. abnormale, onbeheerde bewegings van die ledemate). Indien jy gevorderde Parkinson se siekte het en ook levodopa neem, kan jy diskinesie ontwikkel tydens die optitrering van **PEXSON XR**.
- Distonie (onvermoë om jou liggaam en nek reguit en regop te hou (aksiale distonie)). In die besonder kan jy vooroor buiging van die kop en nek ervaar (ook genoem antekollis), voorwaartse buiging van die lae rug (ook genoem kamptokormia) of sywaartse buiging van die rug (ook genoem pleurototonus of Pisa se sindroom).
- Slaperigheid en episodes van skielik aan die slaap raak.
- Psigose (bv. vergelykbaar met simptome van skisofrenie)
- Visie inkorting. Jy moet gereelde oogondersoeke ondergaan tydens behandeling met **PEXSON XR**.
- Erge hart- of bloedvatsiektes. Jy sal jou bloeddruk gereeld moet laat nagaan, veral aan die begin van die behandeling. Dit is om posturale hipotensie ('n daling in bloeddruk wanneer opstaan) te vermy.

Vertel jou dokter indien jy of jou familie/versorger agterkom dat jy lus of drange ontwikkel om op te tree op maniere wat vir jou ongewoond is en jy nie die impuls, dryfkrag of versoeking kan weerstaan om sekere aktiwiteite uit te voer wat jouself of ander kan skade berokken nie. Dit word impulsbeheerversteurings genoem en kan gedrag soos verslawende dobbelary, oormatige eet of besteding, 'n abnormaal hoë seksdrang of beheptheid met 'n toename in seksuele gedagtes of gevoelens insluit. Jou dokter sal moontlik jou dosis moet aanpas of staak.
Vertel jou dokter indien jy of jou familie/versorger agterkom dat jy manie (rusteloos, opgewonde of uitgelate voel) of delirium (verminderde bewustheid, verwarring of verlies aan werklikheid) ontwikkel. Jou dokter sal moontlik jou dosis moet aanpas of staak.
Vertel jou dokter indien jy of jou familie/versorger agterkom dat jy verslawings-agtige simptome ontwikkel, wat lei tot 'n sterk drang na hoë dosisse van **PEXSON XR** en ander medisyne wat gebruik word om Parkinson se siekte te behandel (bekend as dopamien-disreguleringsindroom).

Gebruik in kinders en adolessente
Die gebruik van **PEXSON XR** in kinders en adolessente (jonger as 18 jarige ouderdom) word nie aanbeveel nie.

Ander medisyne en PEXSON XR
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Neem spesiale sorg indien jy die volgende medisyne neem:
- simetidien (om oortollige maagsuur en maag ulkusse te behandel)
- amantadien (wat gebruik kan word om Parkinson se siekte te behandel)
- meksiletien (om onreëlmatige hartklop te behandel, 'n toestand bekend as ventrikulêre disritmie)
- zidovudien (wat gebruik kan word om die verworwe immuungebreksindroom (VIGS), 'n siekte van die menslike immuunstelsel te behandel)
- sisplatien (om verskillende soorte kankers te behandel)
- kinien (wat gebruik kan word vir die voorkoming van pynlike beenkrampe in die nag en vir die behandeling van 'n tipe malaria bekend as falkiparum malaria (kwaadaardige malaria))
- prokaïnamied (om onreëlmatige hartklop te behandel)
- Indien jy levodopa neem, word die dosis levodopa aanbeveel om verminder te word wanneer jy met die behandeling met **PEXSON XR** begin.
- Jy moet vermy om **PEXSON XR** saam met antipsigotiese medisyne (gebruik vir buie of geestesongesteldheid) te neem

PEXSON XR met alkohol:
Die drink van alkohol kan die slaperigheid wat deur **PEXSON XR** veroorsaak word, vererger.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **PEXSON XR** neem .

Moet nie **PEXSON XR** neem indien jy swanger is, oorweeg om swanger te raak of borsvoed nie.

Bestuur en gebruik van masjinerie
PEXSON XR kan hallusinasies veroorsaak (sien, hoor of voel goed wat nie daar is nie). Indien geaffekteer, moet nie bestuur of masjiene gebruik nie.
PEXSON XR is geassosieer met slaperigheid en episodes van skielik aan die slaap raak, veral in pasiënte met Parkinson se siekte. Indien jy hierdie newe-effekte ervaar, moet jy nie bestuur of masjinerie gebruik nie. Jy moet jou dokter vertel indien dit gebeur.

3. Hoe om PEXSON XR te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **PEXSON XR** presies soos jou dokter jou beveel het. Jy moet met jou dokter of apteker bevestig indien jy nie seker is nie.

Die gewone dosis is 0,375 mg per dag en verhoog dan elke 7 dae, tot op 'n maksimum dosis van 4,5 mg per dag indien nodig.
PEXSON XR moet slegs een keer per dag mondelings ingeneem word en heel met water ingesluk word.

Jou dokter sal jou vertel hoe lank behandeling met **PEXSON XR** sal duur.
Indien jy die indruk het dat die effek van **PEXSON XR** te sterk of te swak is, praat met jou dokter of apteker.
Indien jy meer PEXSON XR 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.
Indien jy vergeet om PEXSON XR te neem
Dit is belangrik om jou **PEXSON XR** gereeld op dieselfde tyd elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse gelyktydig neem, om op te maak vir 'n vergete dosis nie.
Indien jy ophou om PEXSON XR te neem
Indien **PEXSON XR** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **PEXSON XR** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

PEXSON XR kan newe-effekte hê.
Nie alle newe-effekte wat vir **PEXSON XR** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **PEXSON XR** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om PEXSON XR te neem en lig onmiddellik jou dokter in of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk en asem te haal.
- Uitslag of gejeuk.
- Floute.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, het jy dalk 'n ernstige allergiese reaksie op **PEXSON XR** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.

Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Koors, borskaspyn

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

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereeld
- Slapeloosheid (insomnie)
- Hallusinasies (sien, hoor of voel goed wat nie daar is nie)
- Abnormale drome
- Drang om op 'n ongewone manier op te tree
- Verwarring
- Diskinesie (bv. abnormale, onbeheerde bewegings van die ledemate)
- Slaperigheid
- Duiseligheid
- Hoofpyn
- Hipotensie (lae bloeddruk)
- Naarheid (siekte)
- Braking (siek wees)
- Hardlywigheid
- Moegheid (vermoeidheid)
- Oormaat van vloeistof, gewoonlik in die bene (periferiese edeem)
- Gewigsverlies insluitend verminderde eetlus

Minder gereeld:
- Pneumonie (infeksie van die longe)
- Onvanpaste anti-diuretiese hormoonafskeiding
- Onvermoë om die impuls, dryfkrag of versoeking te weerstaan om 'n aksie uit te voer wat skadelik vir jou of ander kan wees, wat kan insluit:
- Sterk impuls om oormatig te dobbel ten spyte van ernstige persoonlike of gesinsgevolge.
- Veranderde of verhoogde seksuele belangstelling en gedrag van beduidende belang vir jou of vir ander, byvoorbeeld 'n verhoogde seksuele drang.
- Onbeheerbare oormatige inkopies of besteding
- Binge eet (eet groot hoeveelhede kos in 'n kort tydperk) of kompulsiewe eet (eet meer kos as normaal en meer as wat nodig is om jou honger te bevredig)
- Delirium (verminderde bewustheid, verwarring, verlies aan werklikheid)
- Paranoïes (bv. oormatige vrees vir een se eie welstand)
- Delusie
- Rusteloosheid
- Oormatige slaperigheid gedurende die dag en skielik aan die slaap raak
- Amnesie (geheueversteuring)
- Hiperkinesie (toename in bewegings en onvermoë om stil te bly)
- Floute
- Hartversaking (hartprobleme wat kort van asem of enkelswelling kan veroorsaak)
- Dispnee (probleme om asem te haal)
- Hik
- Allergiese reaksies (bv. uitslag, gejeuk, hipersensitiwiteit)
- Gewigstoename

Frekwensie onbekend
- Visuele inkorting

Nadat jy jou behandeling **met PEXSON XR** gestaak of verminder het: Depressie, apatie, angs, moegheid, sweet of pyn kan voorkom (genoem dopamienagonis-onttrekkingsindroom of DAWS).

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

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 Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word, of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **PEXSON XR.**

5. Hoe om PEXSON XR te bewaar

Hou by of benede 30°C vir stulpstrokie en hou by of benede 25°C vir houer.
Beskerm teen vog.
Moet nie in 'n yskas bêre nie.
HOU BUITE DIE BEREIK VAN KINDERS.
Stoor in die oorspronklike verpakking/houer.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie '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 PEXSON XR bevat
Die aktiewe bestanddeel is pramipeksool.
Bevat suiker - Mannitol
Die ander bestanddele is:
Hipormellose
Voorafgelatineerde stysel
Karbomeer homopolimeer
Kolloïdale silikondioksied
Magnesiumstearaat

Hoe PEXSON XR lyk en inhoud van die pak
PEXSON 0,375 XR: Witkleurige, sirkelvormige, plat, skuins rande, onbedekte tablet bedruk met 'ER 1' aan die een kant van die tablet en '0,375' aan die ander kant.
PEXSON 0,75 XR: Witkleurige, sirkelvormige, plat, skuins rande, onbedekte tablet bedruk met 'ER 2' aan die een kant van die tablet en '0,75' aan die ander kant.
PEXSON 1,5 XR: Witkleurige, ovaalvormige, bikonvekse, onbedekte tablet bedruk met 'ER 3' aan die een kant van die tablet en '1,5' aan die ander kant.
PEXSON 3 XR: Witkleurige, ovaalvormige, bikonvekse, onbedekte tablet bedruk met 'ER 5' aan die een kant van die tablet en '3,0' aan die ander kant.
PEXSON 4,5 XR: Witkleurige, ovaalvormige, bikonvekse, onbedekte tablet bedruk met 'ER 7' aan die een kant van die tablet en '4,5' aan die ander kant van die tablet.

Inhoud van die pak:
Tablette word verpak in 'n ronde wit 60 HDPE-houer met 'n silikagelsakkie en toegemaak met 'n wit kinderbestande sluiting wat in 'n buitenste karton verpak is. Pakgroottes sluit 28's, 30's tablette in.
Tablette word verpak in aluminiumfoelie wat aan die een kant gelamineer is en aan die ander kant op PVC gelamineer is. Pakgroottes sluit 28's tablette of 30's tablette in. Nie alle verpakkingsgroottes word noodwending bemark nie.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
GRONDVLOER, BLOK 1,
BASSONIA ESTATE KANTOORPARK (OOS),
CUSSONIA-RYLAAN 1,
BASSONIA ROCK, UITBR. 12
ALBERTON
GAUTENG

Hierdie inligtingstuk was laas hersien in
25/11/2025

Registrasienommers
PEXSON 0,375 XR: 58/5.4.1/0016
PEXSON 0,75 XR: 58/5.4.1/0017
PEXSON 1,5 XR: 58/5.4.1/0018
PEXSON 3,0 XR: 58/5.4.1/0019
PEXSON 4,5 XR: 58/5.4.1/0020

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: PEXSON XR (Pramipexole Extended Release Tablet)	
2. Country: South Africa(Private South Africa)	**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: 335 (L) x 310 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM04342086**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 41022 mini**
13. Barcode/NDC No: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. A/W File name:G:\Regulated_Artwork\SOUTH AFRICA\Pramipexole\Private South Africa\Pramipezole ER Tablets - PM04342086.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	02/04/2026				

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/021/04-01

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa (Private South Africa)	**PM04342086**		