1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PEXASP 0,125 mgtablets

PEXASP 0,25 mg tablets

PEXASP 1 mg tablets

Contains sugar: Mannitol 41,55 mg

Read all of this leaflet carefully before you start taking PEXASP because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or your pharmacist, nurse or other healthcare provider.
- PEXASP has been prescribed for you personally and you should not share PEXASP with other people. It may harm them, even if their symptoms are the same as yours

What is in this leaflet:

1. What PEXASP is and what it is used for
2. What you need to know before you take PEXASP
3. How to take PEXASP
4. Possible side effects
5. How to store PEXASP
6. Contents of the pack and other information

1. What PEXASP is and what it is used for

Pramipexole belongs to a group of medicines called 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.

PEXASP is used to treat the symptoms of Parkinson's disease. It may be used alone or in combination with levodopa or other medicines used to treat Parkinson's disease.

PEXASP is also used to treat the symptoms of moderate to severe primary Restless Legs Syndrome (RLS) in adults.

2. What you need to know before you take PEXASP

Do not take PEXASP:

- If you are hypersensitive (allergic) to pramipexole or any of the other ingredients of PEXASP (listed in section 6).
- If you suffer from severe kidney disease.
- If you are below the age on 18 (children and adolescents).

Warnings and precautions

If you suffer from sudden onset of sleep and somnolence (sleepiness), falling asleep during activities of daily living and in some cases without warning.

- if you suffer from kidney disease (a reduced dose may be needed).
- if you suffer from hallucinations and confusion (seeing, hearing or feeling things that are not there). Most hallucinations are visual. The elderly are at a greater risk than younger patients.
- if you suffer from 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 gradual increase in the dose of PEXASP.
- if you suffer from 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).
- if you suffer from mania and delirium (some symptoms include becoming very depressed, mood swings as well as disorientation, 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.
- if you suffer from psychosis (e.g. comparable with symptoms of schizophrenia such as by thoughts or experiences that seem out of touch with reality, disorganised speech or behaviour and decreased participation in daily activities. Difficulty with concentration and memory may also be present.
- if you experience any vision difficulties. You should have regular eye examinations during treatment with PEXASP.
- if you suffer from any severe heart or blood vessels disease (cardiovascular). You will need to have your blood pressure checked regularly, especially at the beginning of

treatment. This is to avoid postural or orthostatic hypotension (a fall in blood pressure on standing up).

if you experience augmentation. You may experience that symptoms start earlier than usual, be more intense and involve other limbs.

- 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.
- if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your PEXASP treatment. If the problems persist more than a few weeks, your doctor may need to adjust your treatment.
- if needed to prevent the occurrence of nausea, you may take PEXASP with food.
- when treatment is abruptly stopped; stopping/ withdrawal of PEXASP can lead to symptoms suggestive of neuroleptic malignant syndrome (NMS) which may show as very high fever, irregular pulse, accelerated heartbeat (tachycardia), increased rate of respiration (tachypnea).
- if you experience Dopamine dysregulation syndrome (DDS) is an addictive disorder that has been observed in some patients treated with PEXASP. Patients affected exhibit the compulsive abuse of dopaminergic medicines, using higher doses than are necessary for the adequate control of motor symptoms from Parkinson's disease. In some cases, this may result in severe dyskinesia (see above).

Children and adolescents

PEXASP is not recommended for use in children or adolescents under 18 years (see section 4.2).

Other medicines and PEXASP

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- cimetidine (to treat excess stomach acid and stomach ulcers)
- amantadine (which can be used to treat Parkinson's disease)
- mexiletine, procainamide (to treat irregular heartbeats, a condition known as ventricular dysrhythmia)
- zidovudine (which is treatment in HIV), 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 heartbeat)
- metoclopramide (used to treat nausea)

- If you are taking levodopa, the dose of levodopa is recommended to be reduced when you start treatment with PEXASP.
- Take care if you are using any medicines that calm you down (have a sedative effect) or if you are drinking alcohol. In these cases, PEXASP may affect your ability to drive and operate machinery.
- If you are taking medicines for mental disease. You should avoid taking PEXASP together with antipsychotic medicines such a phenothiazines, butyrophenones, thioxanthenes.

PEXASP with food and drink

You should be cautious while drinking alcohol during treatment with PEXASP.

PEXASP can be taken with or without food however patients advised to take PEXASP with food to reduce the occurrence of nausea.

Pregnancy, breastfeeding and fertility

The safety of PEXASP during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking PEXASP.

Driving and using machines

Since adverse reactions such as hallucinations, somnolence and visual disturbances have been reported in patients receiving PEXASP, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that PEXASP does not adversely affect your ability to do so (see section 4).

PEXASP contains mannitol

Mannitol may have a laxative effect**.**

3. How to take PEXASP

Always take PEXASP exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

You can take PEXASP with or without food. Swallow the tablets with water.

Parkinson's disease: The daily dose is administered in equally divided doses three times a

day.

Patients with kidney disease

The dose of PEXASP may need to be reduced in patients with kidney disease. Your doctor will prescribe a lower dose.

Patients on concomitant levodopa therapy

The dose of levodopa should be reduced during escalation and maintenance dosing with PEXASP.

Restless Legs Syndrome (RLS): The recommended dose is taken once daily.

Your doctor will tell you how long your treatment with PEXASP will last. Do not stop taking PEXASP without talking to your doctor. If you have to stop taking PEXASP, your doctor will reduce the dose gradually.

If you take more PEXASP 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.

You may experience nausea (feeling sick), vomiting, restlessness, uncontrollable muscle movement, hallucinations (seeing, hearing or feeling things that are not there) and low blood pressure (see section 4)

If you forget to take PEXASP

Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking PEXASP

If you suffer from Parkinson's disease you should not stop treatment with PEXASP abruptly. Do not stop treatment early as PEXASP should be tapered off over several days.

A sudden stop could cause you to develop a medical condition called neuroleptic malignant syndrome. The symptoms include loss of muscle movement, rigid muscles, fever, unstable blood pressure, increased heart rate, confusion and depressed level of consciousness (e.g. coma).

If you stop or reduce PEXASP you may also develop a medical condition called dopamine agonist withdrawal syndrome.
The symptoms include depression, apathy, anxiety, fatigue, sweating or
pain. If you experience these symptoms you should contact your healthcare professional..

4. POSSIBLE SIDE EFFECTS

PEXASP can cause side effects.
Not all side effects reported for PEXASP are included in this leaflet. Should your general health worsen while taking PEXASP, please consult your doctor, pharmacist or other healthcare provider for advice.
If any of the following happens, stop using PEXASP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of face, tongue or throat, which may cause difficulty in swallowing or 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 PEXASP. 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:

- yellowing of the skin and eyes, also called jaundice,
- chest pain, tightness in chest, shortness of breath (can be caused by heart failure), wheezing, troubled or difficulty in breathing,
- changes in the way your heart beats, for example, if you notice it beating faster,
- frequent, difficult, burning or painful urination, bloody or cloudy urine,
- swelling of body, arms or legs,
- loss of sense of touch,

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:

- constipation, feeling sick (nausea), vomiting (being sick), dry mouth, tooth disease, heartburn, heartburn, flatulence (intestinal gas), taste changes,
- indigestion,
- loss of appetite, weight loss;
- trouble in sleeping, changes in sleep pattern, such as sleeplessness (insomnia) and sleepiness,
- confusion, memory loss, hallucinations (seeing, hearing or feeling things that are not there), mood or mental changes, abnormal dreams,
- changes in sexual drive or ability,
- unwell feeling, dizziness, drowsiness, unusual tiredness or weakness, physical weakness and lack of energy;

- twitching, twisting, writhing, unusual or difficult body movements (dyskinesia),
- headache,
- double vision or changes in vision, blurred vision, visual impairment,
- ringing in the ears,
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting (postural hypotension),
- runny nose, sinusitis;
- sweating, fever,
- joint pain, muscle weakness, leg cramps,
- increase in enzymes as determined by blood tests,
- loss of bladder control,
- bladder infection,

Less frequent side effects:

- inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
  - pathological gambling (a strong impulse to gamble excessively despite serious personal or family consequences),
  - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal),
  - uncontrollable excessive shopping or spending,
  - delirium (decreased awareness, confusion, loss of reality),
- inappropriate antidiuretic hormone secretion (a condition where the balance of water and salt in the body is off),
- mania (feeling elated or over-excited which causes unusual behaviour),
- restlessness or the need to keep moving (hyperkinesia),
- falling asleep without warning or excessive daytime sleepiness,

- weight increase,
- urge to behave in an unusual way,
- hiccups,
- paranoia (e.g. excessive fear for one's own well-being).

Side effects with unknown frequency

- after stopping or reducing your PEXASP treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS)
- abnormal great desire for food,
- dopamine dysregulation syndrome (DDS) is an addictive disorder that has been observed in some patients treated with PEXASP.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of PEXASP.

5. How to store PEXASP

Store at or below 25 °C.

Protect from light and moisture.

Keep blister in carton until required for use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

6. Contents of the pack and other information

The active substance is 0,125 mg/ 0,25 mg/ 1 mg of active ingredient.

The other ingredients are magnesium stearate, mannitol, microcrystalline cellulose (pH 102), povidone K30, purified talc, starch partially pregelatinised.

Contains sugar: Mannitol 41,55 mg

What PEXASP looks like and contents of the pack

PEXASP 0,125 mg (tablet)

White, round tablets, marked on one side with a “0” (zero)

PEXASP 0,25 mg (tablet)

White, round tablets, marked on one side with a “1” (one), scored on the other side

PEXASP 1 mg (tablet)

White, round tablets, marked on one side with a “3” (three), scored on the other side

100 tablets are packed in polyvinylchloride blister strips sealed with an aluminium foil and polyamide film (OPA) backing.

There are 10 tablets per blister strip and ten strips are packed into an outer cardboard carton together with a leaflet.

REGISTRATION NUMBER

PEXASP 0,125 mg: 42/5.4.1/1023

PEXASP 0,25 mg: 42/5.4.1/1022

PEXASP 1 mg: 42/5.4.1/1024

Holder of the Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

04 May 2021

REGISTRATION NUMBER

PEXASP 0,125 mg: 42/5.4.1/1023

PEXASP 0,25 mg: 42/5.4.1/1022

PEXASP 1 mg: 42/5.4.1/1024

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088