PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 5

XEPLION® 25 mg

XEPLION® 50 mg

XEPLION® 75 mg

XEPLION® 100 mg

XEPLION® 150 mg

(Paliperidone palmitate) *Long-Acting Suspension for Intramuscular Injection*

Sugar free

Read all of this leaflet carefully before you are given XEPLION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- XEPLION 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 XEPLION is and what it is used for**
2. **What you need to know before you use XEPLION**
3. **How to use XEPLION**
4. **Possible side effects**

PATIENT INFORMATION LEAFLET

5. How to store XEPLION

6. Contents of the pack and other information

1. What XEPLION is and what it is used for

What XEPLION is

The actual medicine in XEPLION is paliperidone palmitate

XEPLION is an extended release suspension for intramuscular injection

What XEPLION is used for

XEPLION belongs to the class of antipsychotic medicines and is used to treat schizophrenia in adults (18 years of age and older) XEPLION is used to keep the disorder under control, i.e. to prevent its recurrence.

2. What you need to know before you use XEPLION

Do not receive XEPLION:

- If you are allergic to paliperidone tablets or any other ingredient in XEPLION (See under **WHAT XEPLION CONTAINS)**.
- If you are allergic to risperidone.
- If you have Parkinson's disease or Dementia with Lewy Bodies.
- If you have a moderate to severe loss of kidney function.

Warnings and precautions

Take special care with XEPLION

Elderly Patients

XEPLION has not been studied in elderly patients with dementia. However, elderly patients with dementia may have an increased risk of stroke or death.

All Patients

If you have any of the following conditions, talk to your doctor as he/she may want to adjust your dose or monitor you for a while.

- if you have ever been diagnosed with a condition whose symptoms include high temperature and muscle stiffness (also known as Neuroleptic Malignant Syndrome).
- if you have ever experienced abnormal movements of the tongue or face (Tardive Dyskinesia).
- if you are at risk for diabetes or high blood sugar.
-If you have had breast cancer or a tumour in the pituitary gland in your brain.
- if you have heart disease or heart disease treatment that makes you prone to low blood pressure, or are prone to drop in blood pressure or feeling dizzy when you stand up from lying or sitting positions.
- if you have epilepsy.
- if you have or have had low white blood cell counts in your blood. Let your doctor know right away if you develop a fever or infection while being treated with XEPLION.
- if you have a loss of kidney function. Your doctor may reduce your dose of XEPLION if your kidney function is reduced.
- if you have a loss of liver function.
- if you have prolonged and/or painful erection.
- if you have had problems with body temperature regulation.

- if you have an abnormally high level of the hormone prolactin in your blood or if you have a possible prolactin-dependent tumour.

- if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs have been seen in patients taking XEPLION. Blood clots in the lungs can be fatal.

- Even if you have previously tolerated oral paliperidone or risperidone, very rarely allergic reactions occur after receiving injections of XEPLION. Seek medical attention right away if you experience a rash, swelling of your throat, itching, or problems breathing as these may be signs of a serious allergic reaction.

As dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen with patients taking XEPLION, your doctor may check your white blood cell counts.

XEPLION may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight.
As diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking XEPLION, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.

Since XEPLION may reduce your urge to vomit, there is a chance that it may mask the body's normal response to ingestion of toxic substances or other medical conditions.

During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the

colored part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are receiving XEPLION.

XEPLION is not for treating children and adolescents under 18 years of age.

Children and adolescents

This medicine is not for people who are under 18 years old.

Other medicines and XEPLION

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

Alcohol should be avoided whilst using XEPLION.

Since XEPLION can make you sleepy or drowsy, care should be taken when XEPLION is taken with other medicines that can also cause sleepiness or drowsiness.

Since XEPLION can lower blood pressure, care should be taken when XEPLION is taken with other medicines that lower blood pressure.

XEPLION can reduce the effect of medicines against Parkinson's disease and restless legs syndrome (e.g., levodopa).

XEPLION should be used with caution with medicines that increase the activity of the central nervous system (e.g. psychostimulants such as methylphenidate)

XEPLION may cause an electrocardiogram (ECG) abnormality demonstrating a long time for an electrical impulse to travel through a certain part of the heart (known as "QT prolongation"). Other medicines that have this effect include some medicines used to treat

the rhythm of the heart or to treat infection, and other antipsychotics. It is important to notify your doctor of any medicines you are taking to treat such conditions.

If you are prone to develop convulsions, XEPLION may increase your chance of experiencing them. Other medicines that have this effect include some medicines used to treat depression or to treat infection, and other antipsychotics. It is important to notify your doctor of any medicines you are taking to treat such conditions.

Pregnancy and breastfeeding

The safety of intramuscularly-injected XEPLION for use during human pregnancy has not been established.

Women should not breast-feed a baby during treatment.

Tell your doctor if you are pregnant, think you may be pregnant, or planning to become pregnant before taking this medicine. You should not take XEPLION during pregnancy unless this has been discussed with your doctor. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, or difficulty in feeding may occur in your newborn baby if you used XEPLION in the last trimester of your pregnancy.

Driving and using machines

XEPLION might affect your alertness and may affect your vision. You are, therefore, advised not to drive or operate machines before you know how sensitive you are to XEPLION.

XEPLION contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use XEPLION

If you have never before taken XEPLION, paliperidone or risperidone, your doctor will need to make sure you can tolerate the medicine by giving you an oral dosage form daily for a few days before starting XEPLION.

How and when to take XEPLION

XEPLION is a long-acting medicine that a healthcare professional will give you by injection. This means that you do not have to take this medicine every day. When you receive your first dose of XEPLION, you will need to get a second dose one week later. After that you will only need to get a dose once a month.

Your doctor or healthcare provider will give you the injection into the muscle of your upper arm or buttocks.

Your doctor will tell you how long your treatment with XEPLION will last. Do not stop treatment early. If you are under the impression that the effect of XEPLION is too strong or too weak, tell your doctor or pharmacist.

If you take more XEPLION than you should

Patients who have been given too much XEPLION may experience the following symptoms: Drowsiness or sleepiness, fast heart rate, low blood pressure, an abnormal electrocardiogram (electrical tracing of the heart) or slow or abnormal movements of the face, body, arms or legs.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take XEPLION

It is very important to keep all your appointments and get your injections on time. If you think you are going to miss your appointment, call your doctor or treatment team as soon as you can. Your doctor or treatment team will decide what you should do next.

If you stop taking XEPLION

If you stop going for your injections, your symptoms may return. You should not stop receiving injections of this medicine unless you have discussed this with your doctor.

Patients with kidney or liver impairment:

If you have mild kidney problems your doctor may give you a lower dose. If you have moderate or severe kidney problems XEPLION should not be used.

If you have severe liver problems XEPLION should be used with caution.

4. Possible side effects

XEPLION can cause side effects.

You may experience a severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes drop in blood pressure (amounting to an ‘anaphylactic reaction’). If this should occur, seek medical attention immediately.

PATIENT INFORMATION LEAFLET

Even if you have previously tolerated oral risperidone or oral paliperidone, allergic reactions may occur after receiving injections of XEPLION. Seek medical attention right away if you experience a rash, swelling of your throat, itching, or problems breathing as these may be signs of a serious allergic reaction.

Tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body). Tell your doctor immediately if you experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of XEPLION may be needed.

In elderly patients with dementia, medicines in the same group as XEPLION have been associated with side effects including sudden weakness or numbness of the face, arms, or legs, instances of slurred speech, or blurred vision. These symptoms may be associated with stroke. If any of these should occur, even for a short period of time, seek medical attention immediately (see ~~section 2~~, take special care with XEPLION).

The most frequently reported side-effects are:

Difficulty falling or staying asleep, headache.

Common cold symptoms, urinary tract infection, feeling like you have the flu.

XEPLION can raise your levels of a hormone called "prolactin" found on a blood test (which may or may not cause symptoms). When symptoms of high prolactin occur, they may include in men.

Breast swelling, difficulty in getting or maintaining erections, or other sexual dysfunction. In women they may include breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle.

High blood sugar, weight gain, weight loss, high blood triglycerides (a fat).

Irritability, depression, anxiety.

Parkinsonism: This condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement "freezing up" and then restarting. Other signs of Parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face.

Restlessness, feeling sleepy, or less alert.

Dystonia: This is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue or jaw. Dizziness.

Dyskinesia: This is a condition involving involuntary muscle movements, and can include repetitive spastic or writhing movements, or twitching.

Tremor (shaking).

Slow heart rate, rapid heart rate.

High blood pressure.

Cough, stuffy nose.

Abdominal pain or discomfort, vomiting, nausea, constipation, diarrhoea, indigestion, toothache.

Increased liver transaminases in your blood.

Rash.

Bone or muscle ache, back pain.

Fever, weakness, fatigue (tiredness).

A reaction at the injection site, including itching, pain or swelling.

Less frequent side-effects include:

Pneumonia, infection of the chest (bronchitis), infection of the breathing passages, sinus infection, bladder infection, ear infection, eye infection, tonsillitis, infection of the skin, skin inflammation caused by mites, abscess under the skin.

White blood cell count decreased, anaemia, decrease in red blood cells, increase in eosinophils (a type of white blood cell) in your blood.

Allergic reaction.

Diabetes or worsening of diabetes, increased insulin (a hormone that controls blood sugar levels) in your blood.

Increased appetite, loss of appetite resulting in malnutrition and low body weight, increased or decreased appetite.

Increased cholesterol in your blood.

Sleep disorder, elated mood (mania), confusion, decreased sexual drive, nightmares.

Convulsion (fits), fainting, a restless urge to move parts of your body, dizziness upon standing, disturbance in attention, problems with speech, loss or abnormal sense of taste, reduced sensation of skin to pain and touch, a sensation of tingling, pricking, or numbness of skin.

Blurry vision, eye infection or "pink eye", dry eye.

Sensation of spinning (vertigo), ringing in the ears, ear pain.

Atrial fibrillation (an abnormal heart rhythm), an interruption in conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart,

prolongation of the QT interval from your heart, rapid heartbeat upon standing, abnormal electrical tracing of the heart. (electrocardiogram or ECG), a fluttering or pounding feeling in your chest (palpitations).

Low blood pressure, low blood pressure upon standing (consequently, some people taking XEPLION may feel faint, dizzy, or may pass out when they stand up or sit up suddenly).

Shortness of breath, lung congestion, wheezing, sore throat, nosebleeds. Stomach or intestinal infection, dry mouth, excessive passing of gas or wind.

Increased GGT (a liver enzyme called gamma-glutamyltransferase) in your blood.

Increased liver enzymes in your blood.

Hives (or "nettle rash"), itching, hair loss, eczema, dry skin, skin redness, acne.

Muscle spasms, joint stiffness, neck pain, joint pain.

Incontinence (lack of control) of urine, frequent passing of urine, pain when passing urine.

Erectile dysfunction, ejaculation disorder, loss of menstrual periods, a delay in menstrual periods, missed menstrual periods or other problems with your cycle (females), development of breasts in men, leakage of milk from the breasts, sexual dysfunction, breast discomfort, vaginal discharge.

Swelling of the face, mouth, eyes, or lips, swelling of the body, arms or legs.

A change in the way you walk.

Chest discomfort, feeling unwell.

Hardening of the skin.

Fall.

Other:

Allergic reactions even if you have previously tolerated oral paliperidone or risperidone

Not moving or responding while awake (catatonia); Sleep walking

Sleep related eating disorder

Lack of bowel muscle movement that causes blockage.

Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you have taken XEPLION during the last three months. If you need to have cataract surgery, be sure to tell your eye doctor if you have taken XEPLION during the last three months.

Severe or life-threatening rash with blisters and peeling skin that may start in and around the mouth, nose, eyes, and genitals and spread to other areas of the body (Stevens-Johnson syndrome or toxic epidermal necrolysis)

The following side-effects have been seen with the use of another medicine called risperidone that is very similar to XEPLION, so these can also be expected with XEPLION: other types of blood vessel problems in the brain, crackly lung sounds, dead skin cells at the injection site, and an ulcer at the injection site

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

PATIENT INFORMATION LEAFLET

Reporting of side effects

If you get side effects, talk to your doctor, 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 XEPLION.

5. How to store XEPLION

Store all medicines out of the reach of children.

Store at or below 25°C. Protect from light. Keep in outer carton until ready to use.

XEPLION is for single use only. Any unused portion should be discarded.

Do not use after the expiry date on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What XEPLION contains

The active substance is paliperidone.

Each pre-filled syringe contains sterile paliperidone palmitate equivalent to 25 milligrams of paliperidone.

Each pre-filled syringe contains sterile paliperidone palmitate equivalent to 50 milligrams of paliperidone.

PATIENT INFORMATION LEAFLET

Each pre-filled syringe contains sterile paliperidone palmitate equivalent to 75 milligrams of paliperidone.

Each pre-filled syringe contains sterile paliperidone palmitate equivalent to 100 milligrams of paliperidone.

Each pre-filled syringe contains sterile paliperidone palmitate equivalent to 150 milligrams of paliperidone

The other ingredients are:

The other ingredients are citric acid monohydrate, disodium hydrogen phosphate anhydrous, polyethylene glycol 4000, polysorbate 20, sodium dihydrogen phosphate monohydrate, sodium hydroxide, water for injection.

What XEPLION looks like and contents of the pack

Prolonged-release suspension in prefilled syringes. The suspension is white to off-white, free from visible foreign material. The suspension is homogenous after shaking.

Each pack contains 1 pre-filled syringe and 2 needles.

Kit containing a syringe (cyclic-olefin-copolymer) prefilled with either 25 mg(0.25 ml), 50 mg (0.5 ml), 75 mg (0.75 ml), 100 mg (1.0 ml), or 150 mg (1.5 ml) paliperidone (as 39 mg, 78 mg, 117 mg, 156 mg, or 234 mg paliperidone palmitate) suspension with a plunger stopper and tip cap (bromobutyl rubber), a 1 ½-inch 22 gauge safety needle, and a 1-inch 23 gauge safety needle.

PATIENT INFORMATION LEAFLET

The leaflet was revised in

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Holder of Certificate of Registration

JANSSEN PHARMACEUTICA (PTY) LTD

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Registration/Application number(s)

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XEPLION® 50 mg – 44/2.6.5/0866

XEPLION® 75 mg – 44/2.6.5/0867

XEPLION® 100 mg – 44/2.6.5/0868

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50 mg: 14/2.6.5/0019

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NS 3

Botswana Reg No:

50 mg: BOT 2404282

75 mg: BOT 2404271

100 mg: BOT 2404306

150 mg: BOT 2404301

Schedule 2

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.