

Package leaflet: Information for the user

***Palladone*[®] SR 2 mg, 4 mg and 8 mg prolonged-release capsules**

Hydromorphone hydrochloride

This medicine contains hydromorphone which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What ***Palladone SR*** capsules are and what they are used for
2. What you need to know before you take ***Palladone SR*** capsules
3. How to take ***Palladone SR*** capsules
4. Possible side effects
5. How to store ***Palladone SR*** capsules
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1. What *Palladone SR* capsules are and what they are used for

This medicine has been prescribed for you for the relief of severe pain. It contains hydromorphone, which belongs to a class of medicines called opioids, which are 'pain relievers'. The medicine has been prescribed for you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take *Palladone SR* capsules

Do not take *Palladone SR* capsules if you:

- are allergic to hydromorphone or to any of the other ingredients of the capsules (listed in section 6);
- have breathing problems, such as severe chronic obstructive airways disease, respiratory depression or severe asthma. Symptoms may include breathlessness, coughing or breathing more slowly and weakly than expected;
- have a severe pain in your abdomen;
- have liver problems;
- have a condition where the small bowel does not work properly (paralytic ileus);
- are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;
- are under 12 years of age.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital that you are taking these capsules. Your doctor may adjust your treatment. These

tablets/capsules should not be used for short-term pain after an operation owing to the increased risk of dependence and breathlessness.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating when you have stopped taking alcohol or drugs;
- feel you need to take more **Palladone SR** capsules to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever;
- have breathing problems, such as severely impaired pulmonary function, chronic obstructive airways disease or reduced respiratory reserve. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness and coughing;
- have a severe headache or feel sick due to a head injury or increased pressure in your skull (for instance due to brain disease). This is because the capsules may make symptoms worse or hide the extent of a head injury;
- suffer from seizures, fits or convulsions;
- have a mental disorder as a result of an infection (toxic psychosis);
- have inflammation of the pancreas (which causes severe pain in the abdomen and back);
- have an under-active thyroid gland (hypothyroidism);
- have low blood pressure (hypotension);
- have kidney problems;
- have poor adrenal gland function (your adrenal gland is not working properly which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick);
- have prostate problems;
- are suffering from shock (this may make you suddenly feel very lightheaded, faint, cold or clammy and look pale).
- suffer from constipation
- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- are a smoker.
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

This medicine may cause breathing problems or worsen already existing problems while sleeping. These problems may include pauses in breathing during sleep, being awoken by shortness of breath, difficulty staying asleep or excessive daytime drowsiness. If you or someone else observes these symptoms contact your doctor. Your doctor may want to lower your dose.

This medicine contains hydromorphone which is an opioid medicine. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). Repeated use of **Palladone SR** capsules may lead to dependence and abuse which may result in life threatening overdose. If you have concern that you may become dependent on **Palladone SR** capsules, it is important that you consult your doctor.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

You may experience hormonal changes while taking these capsules. Your doctor may want to monitor these changes.

Other medicines and *Palladone SR* capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you take these capsules with some other medicines, the effect of the capsules or the other medicine may be changed.

These capsules must not be used together with a type of medicine known as a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks (see section 2 'Do not take...').

Tell your doctor or pharmacist if you are taking:

- medicines to help you sleep or stay calm (for example benzodiazepines, tranquillisers, hypnotics or sedatives);
- medicines known as barbiturates to either treat fits or to help you sleep;
- medicines to stop you feeling or being sick;
- medicines to treat depression;
- medicines to treat psychiatric or mental disorders (such as neuroleptics);
- other strong analgesics or 'painkillers'.

Also tell your doctor if you have recently been given an anaesthetic.

Concomitant use of ***Palladone SR*** capsules and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening.

However if your doctor does prescribe ***Palladone SR*** capsules together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Sleep-related breathing disorders

Palladone SR capsules can cause sleep-related breathing disorders such as sleep apnea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Palladone SR capsules with alcohol

Drinking alcohol whilst taking **Palladone SR** capsules may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol whilst you are taking **Palladone SR** capsules.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

Do not take **Palladone SR** capsules if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby. If you take **Palladone SR** capsules during pregnancy your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated, such as high-pitched cry, jitteriness, fits, poor feeding and diarrhoea.

Breast-feeding

Do not take **Palladone SR** capsules while you are breastfeeding as hydromorphone passes into breast milk and will affect your baby.

Driving and using machines

These capsules may cause a number of side effects such as drowsiness, which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the capsules, or when changing to a higher dose. If you are affected you should not drive or use machinery.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive while you have this medicine in your body over a specified limit unless you have a defence (called the 'statutory defence').
- This defence applies when:
 - The medicine has been prescribed to treat a medical or dental problem; and
 - You have taken it according to the instructions given by the prescriber and in the information provided with the medicine.
- Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: <https://www.gov.uk/drug-driving-law>.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How to take *Palladone SR* capsules

Always take the capsules exactly as your doctor has told you. The label on your medicine will tell you how many capsules to take and how often.

Adults and children over 12 years of age

The usual starting dose is one 4 mg capsule every 12 hours. However, your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these capsules, discuss this with your doctor.

Children under 12 years of age

Children under 12 years of age should not take the capsules.

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

Your doctor should have discussed with you how long the course of **Palladone SR** capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Swallow your capsules whole with a glass of water. If you prefer, you can open the capsules and sprinkle the contents on to cold soft food, such as yoghurt. You must only take the capsules by mouth. **Do not crush or chew the capsule or the capsule contents.**

***Palladone SR* capsules are designed to work properly over 12 hours. If the capsule contents are crushed, dissolved or chewed, the entire 12-hour dose may be absorbed rapidly into your body. The capsule contents should never be injected. This can be dangerous, causing serious problems such as an overdose, which may be fatal.**

You should take your capsules every 12 hours. For instance, if you take a capsule at 8 o'clock in the morning, you should take your next capsule at 8 o'clock in the evening.

If you take more *Palladone SR* capsules than you should or if someone accidentally swallows your capsules

Call your doctor or hospital straight away as you may need emergency treatment in hospital. People who have taken an overdose may feel very sleepy, sick, dizzy, result in a brain disorder (known as toxic leukoencephalopathy) or get pneumonia from inhaling vomit or foreign matter (symptoms may include breathlessness, cough and fever). They may also have breathing difficulties leading to unconsciousness, or even death.

When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show the doctor.

If you forget to take *Palladone SR* capsules

If you remember within 4 hours of the time your capsule was due, take your capsule straight away. Take your next capsule at your normal time. If you are more than 4 hours late, please call your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten capsule.

If you stop taking *Palladone SR* capsules

Do not suddenly stop taking this medicine. If you want to stop taking this medicine discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased

blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, these capsules can cause side effects, although not everybody gets them.

This medicine can cause allergic reactions. The incidence of serious allergic reactions is not known.

Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, mouth or throat, or any rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression).

Drug withdrawal

When you stop taking **Palladone SR** capsules you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking **Palladone SR** capsules it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber;
- You feel you need to use more than the recommended dose;
- You are using the medicine for reasons other than prescribed;
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs it is important you talk to your doctor.

Most people will have constipation when using this medicine. Increasing the amount of fibre (fruit, vegetables, wholemeal bread, pasta, brown rice) and fluids you eat and drink may help reduce the problem, but if necessary your doctor may prescribe a laxative.

You may feel sick or vomit (be sick) when you use this medicine, this should normally wear off after a few days however your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.

Very common side effects (may affect more than 1 in 10 people)

- Dizziness, constipation, feel sick.
- Drowsiness (this is most likely when you first start taking your capsules or when your dose is increased, but it should wear off after a few days).

Common side effects (may affect up to 1 in 10 people)

- Loss of appetite.
- Confusion, anxiety, difficulty sleeping.
- Headache.
- Being sick, abdominal pain, dry mouth.
- A feeling of unusual weakness.

- Itchy skin, sweating.

Uncommon side effects (may affect up to 1 in 100 people)

- Agitation, depression, hallucinations, nightmares.
- A feeling of extreme happiness.
- Muscle spasms, shaking, tingling in the hands or feet.
- Blurred vision.
- Low blood pressure.
- Shortness of breath.
- Diarrhoea, changes in taste.
- A worsening in liver function tests (seen in a blood test)
- Rash.
- Difficulty in passing urine.
- Impotence.
- Withdrawal symptoms (see section 'Drug withdrawal').
- Tiredness, generally feeling unwell.
- Swelling of the hands, ankles or feet.

Rare side effects (may affect up to 1 in 1,000 people)

- Sedation, lack of energy.
- Fast heartbeat.
- A condition where you breathe more slowly and weakly than expected.

Side effects with unknown frequency (frequency cannot be estimated from the available data)

- Allergic reactions.
- Dependence and addiction (see section 'How do I know if I am addicted?')
- Drug tolerance
- Unpleasant or uncomfortable mood.
- Reduction in size of the pupils in the eye.
- An increase in sensitivity to pain (hyperalgesia; see "Warnings and precautions" in section 2).
- Seizures, fits or convulsions.
- Uncontrolled muscle movements.
- Facial flushing (redness of the face).
- A condition where the small bowel (part of your gut) does not work properly (paralytic ileus).
- Itching rash (hives).
- Withdrawal symptoms in babies born to mothers who have used hydromorphone (see "Pregnancy and breastfeeding" in section 2).
- Sleep apnoea (breathing pauses during sleep).

Reporting of side effects

If you get any 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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *Palladone SR* capsules

Keep this medicine out of the sight and reach of children.

Do not use any capsules after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of that month.

Do not store your capsules above 25°C. Store in the original package.

Do not take your capsules if they are broken or crushed as this can be dangerous and can cause serious problems such as overdose.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What *Palladone SR* capsules contain

The active ingredient is hydromorphone hydrochloride. Each capsule contains 2 mg, 4 mg or 8 mg of hydromorphone hydrochloride.

The other ingredients are:

- Microcrystalline cellulose
- Hypromellose
- Ethylcellulose
- Colloidal anhydrous silica
- Dibutyl sebacate
- Gelatin
- Sodium laurilsulfate
- Shellac
- Propylene glycol
- Titanium dioxide (E171)
- Iron oxide (E172)

The capsules also contain the following colourants:

2 mg capsule – Quinoline yellow (E104)

4 mg capsule – Erythrosine (E127) and indigo carmine (E132)

8 mg capsule – Erythrosine (E127)

What *Palladone SR* capsules look like and the contents of the pack

The capsules have a hard gelatin shell containing spherical pellets. The capsules are marked HCR followed by the strength (e.g. 2, 4 etc.) and are coloured as follows: 2 mg – yellow/ white, 4 mg – pale blue/clear, 8 mg – pink/clear.

In each box there are 56 capsules.

Marketing Authorisation Holder and Manufacturer

The capsules are made by Bard Pharmaceuticals Limited for the marketing authorisation holder Napp Pharmaceuticals Limited, both at Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line (free of charge) on: **0800 198 5000**

You will need to give details of the product name and reference number. These are as follows:

Product name: ***Palladone SR*** prolonged-release capsules

Reference number: 16950/0051

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