Package leaflet: Information for the user

***Palladone*® *SR* 2 mg, 4 mg, 8 mg, 16 mg and 24 mg prolonged-release capsules, hard**
Hydromorphone hydrochloride

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 only. 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What *Palladone SR* is and what it is used for

These capsules have been prescribed for you to relieve severe pain over a period of 12 hours. They contain the active ingredient hydromorphone which is a strong analgesic ('painkiller') that belongs to a group of medicines called opioids.

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

Do not take *Palladone SR* if you:
- are allergic (hypersensitive) to hydromorphone or any of the other ingredients of the capsules (see section 6 'Further Information');
- 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 sudden severe pain in your abdomen (acute abdomen);
- have a condition where the 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.

If you are going to have an operation, please tell the doctor at the hospital that you are taking these capsules.

Warnings and precautions
Before treatment with these capsules tell your doctor or pharmacist if you:
- have breathing problems, such as chronic obstructive airways disease or reduced respiratory reserve. Symptoms may include breathlessness and coughing;
- have sleeping difficulties (sleep apnoea)
- 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 intoxication (toxic psychosis);

- have low blood pressure (hypotension);
- are feeling light headed or faint;
- have gall bladder or bile duct problems;
- have colicky abdominal pain or discomfort;
- have inflammation of the pancreas (which may cause severe pain in the abdomen and back);
- have a blockage of the gut or inflammatory bowel disorder;
- have an enlarged prostate gland, which causes difficulty in passing urine (in men);
- have poor adrenal gland function e.g. Addison's disease (your adrenal gland is not working properly);
- have an under-active thyroid gland (hypothyroidism);
- have severe kidney or liver problems;
- are or have ever been addicted to alcohol or drugs;
- have withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping alcohol or drugs;
- Suffer from a debilitating general condition or are elderly;
- suffer from constipation.

This medicine can cause breathing 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.

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

You may experience increased sensitivity to pain despite the fact that you are taking increasing doses of these capsules (hyperalgesia). Your doctor will decide whether you need a change in dose or a change in strong analgesic ('painkiller').

The capsules or their contents should never be crushed and injected as this may lead to serious side effects, which may be fatal.

Other medicines and *Palladone SR*
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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 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 tranquillisers, hypnotics or sedatives including benzodiazepines);
- medicines known as barbiturates to either treat fits or to help you sleep;
- medicines to stop you feeling or being sick;
- medicines to prevent or relieve the symptoms of an allergy (antihistamines);
- medicines to treat depression;
- medicines to treat psychiatric or mental disorders (antipsychotics such as phenothiazines);
- other strong analgesics ('painkillers').

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

Concomitant use of ***Palladone SR*** 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.

However if your doctor does prescribe ***Palladone SR*** 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.

Taking *Palladone SR* with food, drink and alcohol
These capsules can be taken with or without food.
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 while you're taking ***Palladone SR*** capsules.

Pregnancy and breast-feeding
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 taking this medicine. Newborn babies may suffer withdrawal effects (such as high-pitched cry, jitteriness, fits, poor feeding and diarrhoea) if their mothers have taken hydromorphone for a long time during pregnancy.

Pregnancy
You should not use these capsules during pregnancy and labour unless you have been specifically told by your doctor. Depending on the dose and duration of therapy with hydromorphone slow and shallow breathing (respiratory depression) or withdrawal symptoms may occur in the newborn infant. Withdrawal symptoms in babies born to mothers who have used hydromorphone in pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties, sweating and not putting on weight.

Breast-feeding
These capsules should not be used while breastfeeding because the active ingredient can pass into breast milk.

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.

Palladone SR contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per capsule, i.e. essentially 'sodium free'

3. How to take *Palladone SR*

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.

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

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 foods, such as yoghurt. You must only take the capsules by mouth. **Do not crush or chew the capsule or the capsule contents.**

***Palladone SR* is 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. 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.

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.

Elderly patients and patients with kidney or liver problems
Please tell your doctor if you suffer from kidney or liver problems. Your doctor may prescribe you a lower dose of these capsules if you are elderly, or have kidney or liver problems.

If you take more *Palladone SR* than you should or if someone accidentally swallows your capsules
Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy, sick or dizzy and may also develop pinpoint pupils, breathing problems, low blood pressure or pneumonia caused by inhaling vomit or foreign matter (symptoms may include breathlessness, cough and fever). In severe cases an overdose may lead 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 have taken too many capsules under no circumstances should you put yourself in a situation that requires you to be alert e.g. driving a car.

If you forget to take *Palladone SR*
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*
You should not suddenly stop taking these capsules unless your doctor tells you to. If you want to stop taking your capsules, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant side effects. Withdrawal symptoms such as agitation, anxiety, nervousness, difficulty in sleeping, being unusually overactive, shaking or gastrointestinal disorders (e.g. upset stomach) may occur if you suddenly stop taking these capsules.

If you have any further questions on the use of this product, 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 (hypersensitivity) which may be serious (anaphylactic reactions). The frequency of these reactions is not known. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face, 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 – a typical hazard of an opioid overdose).

As with all strong painkillers, there is a risk you may become addicted or reliant on these capsules.

Very common (may affect more than 1 in 10 people taking these capsules)
- Constipation (your doctor can prescribe a laxative to overcome this problem).
- Feeling sick.

- Dizziness, feeling more sleepy than normal.

Common (may affect up to 1 in 10 people taking these capsules)
- Being sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem).
- Anxiety, confusion.
- Difficulty in sleeping.
- Dry mouth, loss of appetite, abdominal pain or discomfort.
- Headache.
- A feeling of unusual weakness.
- Itchy skin.
- Sweating.
- An urge to pass urine.

Uncommon (may affect up to 1 in 100 people taking these capsules)
- Withdrawal symptoms (see section 3 'If you stop taking ***Palladone SR***').
- Indigestion, diarrhoea, changes in taste.
- Depression, a feeling of extreme happiness, hallucinations, nightmares.
- Blurred vision.
- Agitation.
- Tremor, muscle spasms, tingling or numbness.
- Low blood pressure.
- A shortness of breath.
- Decreased sexual drive, impotence.
- Rash.
- Swelling of the feet, ankles or hands.
- Difficulty in passing urine.
- Generally feeling unwell.
- Tiredness.
- A worsening in liver function tests (seen in a blood test).

Rare (may affect up to 1 in 1,000 people taking these capsules)
- Aggression.
- Feeling far more sleepy than normal.
- Lack of energy.
- A fast heart beat, a slow heart beat, palpitations.
- Wheezing or difficulty in breathing.
- A worsening in pancreas function tests (seen in a blood test).

Not known (frequency cannot be estimated from the available data)
- Problems with breathing during sleep (sleep apnoea syndrome)
- Seizures, fits or convulsions.
- An unpleasant or uncomfortable mood.
- An increase in sensitivity to pain.
- A condition where the bowel does not work properly (paralytic ileus).
- A reduction in size of the pupils in the eye.
- Flushing.
- Uncontrolled muscle movements.
- Hives.
- A need to take increasingly higher doses to gain the same level of pain relief (tolerance).
- Withdrawal symptoms in babies born to mothers who have used hydromorphone (see section 2).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *Palladone SR*

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

Do not use these 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 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What *Palladone SR* contains
The active ingredient is hydromorphone hydrochloride.

Each capsule contains 2 mg of hydromorphone hydrochloride equivalent to 1.78 mg hydromorphone, 4 mg hydromorphone hydrochloride equivalent to 3.56 mg hydromorphone, 8 mg of hydromorphone hydrochloride equivalent to 7.12 mg hydromorphone, 16 mg of hydromorphone hydrochloride equivalent to 14.24 mg hydromorphone, or 24 mg of hydromorphone hydrochloride equivalent to 21.36 mg hydromorphone.

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

The capsule shells also contain the following:
2 mg capsule - Quinoline yellow (E104)
4 mg capsule - Erythrosine (E127) and indigo carmine (E132)
8 mg capsule - Erythrosine (E127)
16 mg capsule - Iron oxide (E172)
24 mg capsule - Indigo carmine (E132)

What *Palladone SR* looks like and the contents of the pack
The capsules have a hard gelatin shell containing white to off-white spherical pellets. The capsules are marked HCR followed by the strength (e.g. 2, 4, 8 etc.) and are coloured as follows:
2 mg - yellow/white,

4 mg - pale blue/clear,
8 mg - pink/clear,
16 mg - brown/clear,
24 mg - dark blue/clear.

The capsules are packed in blister packs and then placed in boxes. In each box there are 56 capsules.

Marketing Authorisation Holder
Mundipharma Pharmaceuticals Ltd., United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Manufacturer
Mundipharma DC B.V., Leusderend 16, 3832 RC Leusden, Netherlands.

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 on:

0044 1733 37 53 70

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

Product name: Palladone SR capsules, hard
Reference number: 1688/7/7

This leaflet was last revised in February 2023.