

## MEDICATION GUIDE

### PALLADONE™ (PAL-ah-doan) (hydromorphone hydrochloride extended-release) Capsules CII 12 mg, 16 mg, 24 mg, 32 mg

**Read the Medication Guide that comes with Palladone™** before you start taking it and each time you get more Palladone. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment. Share this important information with members of your household.

#### **What is the most important information I should know about Palladone™?**

- **Palladone is only for adults with constant (around the clock) pain that is moderate to severe and expected to last for weeks or longer.** Palladone should only be started if you are already using other narcotic medicines and your body has gotten used to them (opioid tolerant). **Palladone can cause serious side effects, including trouble breathing, which can lead to death, especially if used the wrong way.**
- **Palladone is not for occasional ("as needed") use.**
- **Palladone should not be the first opioid (narcotic) pain medicine that is prescribed for your pain.**
- **Palladone is not for patients who need opioid pain medicines for only a short time.**
- **Do not break, crush, dissolve, chew, or open Palladone™ Capsules. Palladone Capsules must be swallowed whole.** Taking a broken, crushed, dissolved, or chewed Palladone capsule or its contents can release the full 24-hour dose into your body all at once. This is very dangerous. You could die from an overdose of the medicine.
- **Keep Palladone in a safe place away from children.** Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes Palladone, call your local Poison Control Center or the nearest emergency room right away.
- **Palladone is an opioid (narcotic) pain medicine.** There is a chance you could get addicted to Palladone. The chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.
- **Palladone™ is a Schedule II, federally controlled substance because it contains an opioid (narcotic) pain medicine** that can be a target for people who abuse

prescription medicines or street drugs. Keep your Palladone in a safe place to protect it from being stolen. Never give Palladone to anyone else, even if they have the same symptoms you have. It may harm them and cause death. Selling or giving away this medicine is against the law.

### **What is Palladone™?**

Palladone™ is a prescription medicine that contains the opioid (narcotic) pain medicine hydromorphone. Palladone™ is a very strong pain medicine. Palladone is used to treat adults (18 years of age and older) with constant (around-the-clock) pain that is moderate to severe and is expected to last for weeks or longer. Palladone should be started only after you have been taking other opioid pain medicines and your body has gotten used to them (opioid tolerant). You must stay under your healthcare provider's care while taking Palladone.

Palladone Capsules are not to be used:

- as the first opioid pain medicine prescribed for you
- if you only need opioid pain medicine for a short time
- for occasional (“as needed”) use

### **Who should not take Palladone™?**

#### **Do Not Take Palladone if:**

- your pain can be taken care of by occasional use of other pain medicines.
- you have acute (sudden) or severe asthma
- you have a stomach problem called a paralytic ileus
- you are allergic to any of the ingredients in Palladone. The active ingredient is hydromorphone. For a complete list of ingredients, see “**What are the ingredients of Palladone?**” at the end of this leaflet.

### **What should I tell my healthcare provider before starting Palladone?**

**Tell your healthcare provider about all of your medical and mental problems, especially the ones listed below:**

- trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
- a head injury
- liver or kidney problems
- seizures (convulsions or fits)
- gallbladder problems
- low thyroid (hypothyroidism)
- low blood pressure
- problems urinating

- mental problems including major depression or hallucinations (seeing or hearing things that are not there)
- adrenal gland problems such as Addison's disease
- a past or present drinking problem or alcoholism, or a family history of this problem
- a past or present drug abuse or addiction problem, or a family history of this problem

#### **Tell your healthcare provider if you are:**

- **pregnant or planning to become pregnant.** Palladone may harm your unborn baby.
- **breast feeding.** Palladone likely passes through your milk and it may cause serious harm to your baby. You and your doctor should decide whether you should take Palladone or breastfeed, but not both.

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening medical problems when taken with Palladone™. Sometimes, the doses of certain medicines and Palladone need to be changed if used together. Be especially careful about other medicines that make you sleepy such as other pain medicines, sleeping pills, anxiety medicines, antihistamines, or tranquilizers.

Do not start any new prescription medicine, non-prescription medicine, or herbal supplement while using Palladone until you have talked to your healthcare provider. Your healthcare provider will tell you if it is safe to take other medicines while you are using Palladone.

#### **How should I take Palladone™?**

- Take Palladone exactly as prescribed.
- **Palladone Capsules must be swallowed whole with water.** If you cannot swallow the capsule whole, tell your healthcare provider who will advise you what to do. **Do not break, chew, dissolve, crush, or open Palladone Capsules or their contents before swallowing.** Taking a broken, chewed, dissolved, or crushed Palladone capsule or its contents can release the full 24-hour dose into your body all at once. This is very dangerous. You could die from an overdose of the medicine.
- Your healthcare provider may change your dose after seeing how the medicine affects you.
- Do not change your dose unless your healthcare provider tells you to change it.
- Do not take Palladone™ more often than prescribed.
- Take Palladone once a day at the same time every day.
- If you miss a dose, take it as soon as possible. Take your next dose 24 hours later. Do not double your prescribed dose of Palladone at any time because this increases your chance of an overdose. If you are not sure what to do, call your healthcare provider.
- **If you take too much Palladone or overdose**, call your local emergency number or Poison Control Center right away, or get emergency help.
- Talk to your healthcare provider often about your pain. Your healthcare provider can decide if your dose of Palladone needs to be changed.

If you continue to have pain or side effects that worry you, call your healthcare provider.

**Stopping Palladone™.** You should not suddenly stop taking Palladone™. Palladone can cause physical dependence. If your healthcare provider decides you no longer need Palladone™, ask how to slowly reduce this medicine so you don't get sick with withdrawal symptoms. **Do not stop taking Palladone without talking to your healthcare provider.** Stopping Palladone suddenly can make you sick with withdrawal symptoms because your body has become used to it. After stopping Palladone according to the instructions of your healthcare provider, flush the unused capsules down the toilet.

### **What should I avoid while taking Palladone™?**

- **Do not drive, operate heavy machinery, or do other dangerous activities** until you know how Palladone affects how alert you are. Palladone™ can make you sleepy. Ask your healthcare provider when it is okay to do these activities.
- **Do not drink alcohol while using Palladone.** It may increase your chance of getting dangerous side effects.
- **Do not take other medicines without talking to your healthcare provider.** Other medicines include prescription and non-prescription medicines, vitamins, and herbal supplements. Be especially careful about medicines that make you sleepy such as other pain medicines, sleeping pills, anxiety medicines, antihistamines, and tranquilizers.
- **Do not breast feed while using Palladone.** Palladone likely passes through your milk and it may cause serious harm to your baby. You and your doctor should decide whether you should take Palladone or breastfeed, but not both.

### **What are the possible or reasonably likely side effects of PALLADONE™?**

Palladone can cause serious side effects including death, especially if used the wrong way. **See "What is the most important information I should know about Palladone?"**

### **Call your healthcare provider or get emergency medical help if you:**

- have trouble breathing
- have extreme drowsiness with slowed breathing
- have shallow breathing (little chest movement with breathing)
- feel faint, dizzy, confused, or have other unusual symptoms

These can be symptoms that you have taken too much (overdose) Palladone or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.

- **Palladone can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down.

- You can develop physical dependence on Palladone. Stopping Palladone suddenly can make you sick with withdrawal symptoms because your body has become used to it. Talk to your healthcare provider about slowly stopping Palladone.
- There is a chance you could get addicted to Palladone. The chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.

**The common side effects of Palladone™** are constipation, nausea, vomiting, nervousness, dizziness, drowsiness, itching, dry mouth, sweating, weakness, and headache. Constipation (not enough or hard bowel movements) is a very common side effect of opioids including Palladone and is unlikely to go away without treatment. Talk to your healthcare provider about the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking Palladone.

Talk to your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of Palladone™. For a complete list, ask your healthcare provider.

### **How should I store Palladone?**

- Store Palladone at room temperature, 59° to 86° F (15° to 30° C).
- Always keep Palladone in a safe place to protect from theft.
- Flush unused or out-of-date Palladone down the toilet.
- **Keep Palladone™ out of the reach of children. Accidental use in children is a medical emergency and can result in death. If a child accidentally takes Palladone, call your local Poison Control Center or go to the nearest emergency room right away.**

### **General information about the safe and effective use of Palladone**

Use Palladone™ only for the pain for which it was prescribed. Do not give Palladone™ to other people, even if they have the same symptoms you have. **Palladone can harm other people and even cause death. Sharing Palladone is against the law.**

This Medication Guide summarizes the most important information about Palladone™. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or other healthcare provider for information about Palladone™ that is written for health professionals or call Purdue Pharma at 1 (888)726-7535.

### **What are the ingredients of Palladone?**

**Active Ingredient: hydromorphone hydrochloride**

**Inactive Ingredients: Pellets** - ammonio methacrylate copolymer type B, ethylcellulose, and stearyl alcohol

NDA 21-044

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**Capsules** - FD&C blue #2 (24 mg strength capsule only), gelatin, red iron oxide (12 mg and 16 mg strength capsules only), synthetic black iron oxide, and titanium dioxide

This Medication Guide has been approved by the U.S. Food and Drug Administration.

**Rx Only**

**Purdue Pharma L.P.**

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