

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

^NJURNISTA[®]

HYDROMORPHONE hydrochloride Prolonged Release Tablets

Read this carefully before you start taking **JURNISTA[®]** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **JURNISTA[®]**.

Serious Warnings and Precautions

- **Even if you take **JURNISTA[®]** as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to overdose and death.**
- **Life-threatening breathing problems can happen while taking **JURNISTA[®]**, especially if not taken as directed.**
- **Never give anyone your **JURNISTA[®]**. They could die from taking it. If a person has not been prescribed **JURNISTA[®]**, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **Babies born to mothers who have taken **JURNISTA[®]** (for short or long periods, in small or large doses) at the end of their pregnancy can suffer life-threatening withdrawal symptoms. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has breathing changes (weak, difficult or fast), is unusually difficult to comfort, has tremors (shakiness), or has increased stools, sneezing, yawning, vomiting, or fever, seek immediate medical help for your baby.**

What is **JURNISTA[®] used for?**

JURNISTA[®] is used for the long-term management of pain, when:

- the pain is severe enough to require daily, around-the-clock painkillers
- the doctor determines that other treatment options are not able to effectively treat your pain

JURNISTA[®] is NOT used (“as needed”) to treat pain that you only have once in a while.

How does **JURNISTA[®] work?**

JURNISTA[®] is a painkiller belonging to a class of medicines known as opioids. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

If you continue to have pain, call your doctor.

Always follow your doctor's instructions carefully and do not change or stop your JURNISTA[®] medication without first consulting with your doctor.

What are the ingredients in JURNISTA[®]?

Medicinal ingredients: HYDROmorphone hydrochloride

Non-medicinal ingredients: butyl hydroxytoluene, cellulose acetate, glycerol triacetate (8 mg, 16 mg and 32 mg only), ferric oxide red (4 mg and 8 mg only), ferric oxide yellow (4 mg, 16 mg, and 32 mg only), hypromellose, iron oxide black, lactose anhydrous, lactose monohydrate (8 mg, 16 mg and 32 mg only), macrogol, magnesium stearate, polyethylene oxide, povidone, propylene glycol, sodium chloride and titanium dioxide

JURNISTA[®] may contain traces of sodium metabisulfite.

JURNISTA[®] comes in the following dosage forms:

4 mg, 8 mg, 16 mg, and 32 mg prolonged-release tablets in hard non-dissolvable shells.

Do not use JURNISTA[®] if:

- you are allergic (hypersensitive) to HYDROmorphone hydrochloride or any of the other ingredients of JURNISTA[®]
- your pain can be controlled by the occasional use of painkillers including those available without a prescription
- you have severe asthma, trouble breathing or other lung problems
- you have bowel blockage or narrowing of the stomach or intestines
- you have had surgery or medical conditions which may have left you with narrowing or “blind loops” in your intestine
- you get sudden severe pain in your abdomen and the cause has not been diagnosed
- you suffer from alcoholism
- you have a head injury or other risks for seizures
- are going to have, or recently had, a planned surgery
- you are also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with JURNISTA[®]
- you are pregnant or plan to become pregnant, breast-feeding, or in labour
- you have a rare inherited disease which affects how your body uses the sugar lactose (because lactose is an ingredient in JURNISTA[®])
- you are under 18 years of age

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JURNISTA[®]. Talk about any health conditions or problems you may have, including if you:

- have any other medical conditions (such as difficulty urinating or breathing or problems with your heart, lungs, brain, liver, hormones, or kidney)
- have inflammatory bowel disease, bowel obstruction, gallbladder disease or bile duct disease

- have problems with your pancreas
- have a history of illicit or prescription drug or alcohol abuse
- you have chronic and severe constipation
- have severe kidney, liver or heart disease
- have low blood pressure
- have problems with your thyroid, adrenal or prostate gland

Other warnings you should know about:

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to JURNISTA[®]. Drowsiness, dizziness, or lightheadedness, can especially occur after the first dose and when the dose is increased.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with JURNISTA[®]:

- alcohol, including prescription and non-prescription medications containing alcohol. Do not drink alcohol while taking JURNISTA[®]. This can lead to drowsiness, depressed breathing, serious side effects or a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by JURNISTA[®]
- other opioid analgesics (for pain)
- general anesthetics (used during surgery)
- benzodiazepines (used to help you sleep or to reduce anxiety)
- illegal drugs
- antidepressants (for depression and mood disorders). Do not take JURNISTA[®] with MAO inhibitors or if you have taken MAOI's in the last 14 days before treatment with JURNISTA[®]
- drugs used to treat serious mental or emotional disorders such as schizophrenia
- antihistamines (for allergies)
- anti-emetics (for prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- some heart medication (beta-blockers)

How to take JURNISTA[®]:

Swallow whole. Do not break, chew, dissolve or crush as it would cause too much drug to be released into your blood at one time and expose yourself to a potentially toxic dose of hydromorphone.

Usual Adult Starting Dose:

Dosage is individualized. Be sure to follow your doctor's dosing instructions exactly.

Take JURNISTA[®] once a day as directed by your doctor. JURNISTA[®] tablets should be taken whole at approximately the same time each day with a glass of water. JURNISTA[®] has a hard, non-dissolvable shell. Do not be alarmed if you notice what appears to be the JURNISTA[®] tablet in your stools, as it is simply the shell.

Overdose:

Early signs of overdose may include abnormally slow or weak breathing, dizziness, confusion or extreme drowsiness or sedation, tiredness, inability to think, talk or walk normally, feeling faint, clammy skin, small pupils or low blood pressure. The effects can get worse and lead to coma (unconsciousness), respiratory failure and death.

If you think you have taken too much JURNISTA[®], contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you miss one dose, take it as soon as possible. However, if it is almost time for your next dose, then skip the missed dose. Do not take two doses at once. If you miss several doses in succession, talk to your doctor before restarting your medication.

Discontinuation of JURNISTA[®]:

Please do not suddenly stop taking JURNISTA[®] as it may cause unwanted side effects such as nausea, vomiting, diarrhea, anxiety and shivering. Your doctor can discuss the best way for you to stop taking JURNISTA[®].

Refilling Prescriptions for JURNISTA[®]:

A new written prescription is required from your doctor each time you need more JURNISTA[®]. Therefore, it is important that you contact your doctor before your current supply runs out.

What are possible side effects from using JURNISTA[®]?

These are not all the possible side effects you may feel when taking JURNISTA[®]. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Drowsiness, insomnia
- Dizziness, fainting
- Nausea, vomiting, poor appetite, dry mouth
- Headache
- Problems with vision
- Weakness, uncoordinated muscle movement
- Itching, skin burning sensation
- Sweating

- Constipation
- Heartburn

Talk with your doctor or pharmacist about ways to prevent constipation when you start using JURNISTA®.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Overdose: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin.			✓
Respiratory Depression: slow, shallow or weak breathing.			✓
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea.			✓
Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		✓	
Fast, Slow or Irregular Heartbeat: heart palpitations.		✓	
Low Blood Pressure: dizziness, fainting, light-headedness.	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect® (www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect® (www.healthcanada.gc.ca/medeffect).

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep unused or expired JURNISTA® in a secure place to prevent theft, misuse or accidental exposure. Keep out of sight and reach of children and pets.

Store JURNISTA® between 15 and 25°C.

Disposal:

JURNISTA® should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about JURNISTA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this patient medication information by visiting the Health Canada website (www.healthcanada.gc.ca); the manufacturer's website www.janssen.com/canada, or by calling 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc.

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