janssen

JURNISTA®
Hydromorphone hydrochloride

DOSAGE FORMS AND STRENGTHS
8 mg tablets:
Red, round, biconvex tablet, with 'HM 8' printed in black ink on one side.
Each tablet contains 8.72 mg and delivers 8 mg hydromorphone HCl, equivalent to 7.12 mg hydromorphone base.

16 mg tablets:
Yellow, round, biconvex tablet, with 'HM 16' printed in black ink on one side.
Each tablet contains 16.35 mg and delivers 16 mg hydromorphone HCl, equivalent to 14.24 mg hydromorphone base.

For excipients, see *List of Excipients.*

CLINICAL INFORMATION
Indications
JURNISTA is indicated for the management of moderate to severe cancer pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time.
JURNISTA is NOT intended for use as an as needed analgesic.
JURNISTA is not indicated for the management of acute or postoperative pain.

DOSAGE AND ADMINISTRATION
As with other opioid analgesics, safe and effective administration of JURNISTA to patients with pain depends upon a comprehensive assessment of the patient. The nature of the pain as well as the concurrent medical status of the patient will affect selection of the dose. Owing to the varied response observed to opioids between individuals, it is recommended that all patients be started at the lowest appropriate dose of opioid therapy and titrated to an adequate level of analgesia, balanced against an acceptable frequency of adverse reactions. The lowest effective dose should be used for the shortest period of time (see *Dosage and Administration – Stopping Treatment*).

As with any strong opioid, appropriate prophylaxis for known adverse reactions (for example constipation), should be considered.

Patients should be instructed to swallow the JURNISTA tablet whole with a glass of water, at approximately the same time each day, and never to chew, divide, or crush it.

JURNISTA should not be taken more than once every 24 hours.

If the patient did not take the regularly scheduled dose of JURNISTA, the patient should be instructed to take the next dose immediately and start a new 24-hour regimen.

Patients currently not routinely receiving opioids
The initial dose in patients currently not routinely receiving opioids should not exceed 8 mg every 24 hours. Some patients may benefit from an initial titration dose of 4 mg every 24 hours to improve tolerability. The dose may be titrated upwards or downwards, if required, in increments of either 4 or 8 mg depending on response and supplementary analgesic requirements. Dose should not be titrated more frequently than every 2 days.

Because it may be more time consuming to titrate a patient to adequate analgesia using a controlled release opioid preparation, it may be advisable to begin treatment with conventional immediate-release preparations (e.g. immediate-release hydromorphone or immediate-release morphine) and then convert to the appropriate total daily dose of JURNISTA. Use the conversion table provided below to calculate the conversion doses (Table 1).

Patients currently receiving opioids regularly
In patients currently taking opioid analgesics, the starting dose of JURNISTA should be based on the prior daily opioid dose, using standard equianalgesic ratios. For opioids other than morphine, first estimate the equivalent total daily dose of morphine, then use Table 1 to determine the equivalent total daily dose of JURNISTA.

Table 1 Multiplication Factors for Converting the Daily Dose of Prior Opioids to the Daily Dose of JURNISTA (mg/day Prior Opioid x Factor = mg/day JURNISTA)

Prior Opioid	Oral Prior Opioid (factor)	Parenteral Prior Opioid (factor)
Morphine	0.2	0.6

Hydromorphone	1	4

No fixed conversion ratio is likely to be satisfactory in all patients, due to individual patient and formulation differences. Therefore, conversion to the recommended starting dose of JURNISTA followed by close patient monitoring and titration should be done.

Dosages should be rounded down to the closest dose of JURNISTA available in 4 mg increments (4, 8, 16, 32, 64 mg tablets), as clinically indicated.

Discontinue all other around-the-clock opioid analgesic medications when JURNISTA therapy is initiated.

JURNISTA can also be safely used with usual doses of non-opioid analgesics and analgesic adjuvants.

Individualization of dosage and maintenance of therapy
After initiation of therapy with JURNISTA, dose adjustments may be necessary to obtain the patient's best balance between pain relief and opioid-related adverse reactions.

If the pain increases in severity or analgesia is inadequate, a gradual increase in dosage may be required. In order to allow the effects of the dose change to stabilize, the dosage should be increased no more frequently than every two days. As a guideline, dosage increases of 25-100% of the current daily dose of JURNISTA should be considered for each titration step.

Once patients become stable on once-daily JURNISTA therapy, the dose may be continued for as long as pain relief is necessary. The continued need for around-the-clock opioid therapy or adjustments in therapy should be reassessed periodically as appropriate.

Stopping treatment
In patients who are physically dependent on opioids and receiving daily administration of hydromorphone, abrupt discontinuation of treatment with JURNISTA will result in symptoms of withdrawal syndrome. There have been reports that rapid discontinuation of opioid analgesics in patients who are physically dependent on opioids has resulted in serious withdrawal symptoms and uncontrolled pain. Therefore, if cessation of therapy with JURNISTA is indicated in patients, the dose of JURNISTA should be reduced by 50% every 2 days until the lowest possible dose is reached, at which time therapy may be safely discontinued. If symptoms of withdrawal appear, tapering should be stopped. The dose should be slightly increased until the signs and symptoms of opioid withdrawal disappear. Tapering should then begin again but with longer periods of time between each JURNISTA dose reduction, or before converting to an equianalgesic dose of another opioid to continue tapering.

Special population
Pediatrics (below age 18)
JURNISTA is not recommended for use in children and adolescents below age 18 due to insufficient data on safety and efficacy (see *Contraindications*).

Elderly
The medical status of the elderly patient is often complex. Therefore, treatment with JURNISTA should be initiated cautiously at a reduced initial dose (see *Pharmacokinetic Properties – Elderly*).

Renal impairment
Following single-dose administration of hydromorphone immediate-release tablets, the following results were observed in clinical studies:
- In patients with moderate renal insufficiency (creatinine clearance of 40-60 mL/min), exposure (plasma AUC) to hydromorphone was approximately 2-times higher than in those with normal renal function and elimination half-life was unaltered.
- In patients with severe renal insufficiency (creatinine clearance < 30 mL/min), exposure (plasma AUC) to hydromorphone was approximately 4-times greater than in those with normal renal function and elimination half-life 3-times longer.

Therefore, patients with either moderate renal insufficiency should be started on a reduced dose and closely monitored during dose titration. In patients with severe renal insufficiency an increased dosing interval should also be considered and these patients should in addition be monitored during maintenance therapy for development of opioid-related adverse reactions.

Hepatic impairment
Following single-dose administration of hydromorphone immediate-release tablets, the following results were observed in clinical studies:

- In patients with moderate hepatic insufficiency (scoring 7-9 on Child-Pugh rating scale) both exposure (plasma AUC) and peak plasma concentrations of hydromorphone were approximately 4-times higher compared with healthy controls and elimination half-life was unaltered.

Therefore, patients with moderate hepatic insufficiency should be started on a reduced dose and closely monitored during dose titration.

CONTRAINDICATIONS

JURNISTA is contraindicated in:

- Patients with a known hypersensitivity to hydromorphone or to any of the tablet excipients.
- Patients who have had surgical procedures and/or underlying disease that would result in narrowing of the gastrointestinal tract, or have "blind loops" of the gastrointestinal tract or gastrointestinal obstruction.
- The management of acute or post-operative pain.
- Patients with status asthmaticus.
- Patients with significant respiratory depression.
- Children, or during pregnancy, labor, and delivery.
- Patients with severely decreased liver function
- Patients with respiratory insufficiency
- Patients with acute abdominal pain of unknown origin
- Concomitant treatment with monoamine oxide (MAO)-inhibitors or within 14 days of stopping such treatment
- Concomitant treatment with buprenorphine, nalbuphine or pentazocine
- Patients in a coma state

WARNINGS AND PRECAUTIONS

Hypotension

Opioid analgesics, including hydromorphone, may cause severe hypotension in an individual whose ability to maintain blood pressure is compromised by a depleted blood volume or concomitant administration of drugs such as phenothiazines or general anesthetics (see *Interactions*).

Paralytic ileus

JURNISTA should not be used in situations with risk of paralytic ileus. If during treatment, paralytic ileus is suspected, treatment with JURNISTA should be stopped. In the case of planned cordotomy or other pain-relieving operations, patients should not be treated with JURNISTA within 24 hours after the operation. Thereafter, a new dose should be used in accordance with the changed need for pain relief if needed.

Impaired respiration

Respiratory depression is the most important hazard of opioid preparations and occurs most frequently in overdose situations, in the elderly, in the debilitated, and in those suffering from conditions accompanied by hypoxia or hypercapnia when even moderate doses may dangerously decrease respiration. JURNISTA, like all other opioids, should be used with extreme caution in patients with a substantially decreased respiratory reserve or pre-existing respiratory depression and in patients with chronic obstructive pulmonary disease. Severe pain antagonizes the respiratory depressant effects of opioids. However, should pain suddenly subside, these effects may rapidly become manifest. Patients who are scheduled for regional anesthetic procedures or other interruptions of pain transmission pathways should not receive JURNISTA within 24 hours of the procedure.

Opioids can cause sleep-related breathing disorders such as sleep apnea syndromes (including central sleep apnea [CSA]) and hypoxia (including sleep-related hypoxia) (see *Adverse Reactions*). Opioid use increases the risk of CSA in a dose-dependent fashion. Evaluate patients on an ongoing basis for the onset of a new sleep apnea, or a worsening of an existing sleep apnea. In these patients, consider reducing or stopping the opioid treatment if appropriate, using best practices for tapering of opioids. (see *Dosage and Administration, Stopping Treatment*).

Central Nervous System (CNS) Depressants, including Alcohol and some Illegal Drugs

The concomitant use of JURNISTA with CNS depressants, including opioid analgesic, alcohol and some illegal drugs, may disproportionately increase the CNS depressant effects, such as profound sedation, respiratory depression or failure, coma and death. If concomitant use of JURNISTA with CNS depressant is clinically necessary, prescribe the lowest effective dosages and minimum duration for both drugs, and follow patients closely for signs of respiratory depression and sedation (see *Interactions*).

Since alcohol increases the sedative effect of hydromorphone concomitant use of JURNISTA and alcohol should be avoided.

Head injury and increased intracranial pressure

The respiratory depressant effects of opioids with carbon dioxide retention and secondary elevation of cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury or raised intracranial pressure. Opioids produce effects that may obscure neurological signs of further increases in intracranial pressure in patients with

head injuries. JURNISTA should only be administered under such circumstances when considered essential and then with extreme caution.

Gastrointestinal tract and other smooth muscle
Like other opioids, hydromorphone causes a reduction in gastrointestinal motility associated with an increase in smooth muscle tone. Consequently, constipation is a frequent side effect reported with treatment with opioids. Patients should be advised on measures to prevent constipation and prophylactic laxative use should be considered. Extra caution should be used in patients with chronic constipation.

Clinical conditions or medicinal products that cause a sudden and significant shortening of gastrointestinal transit time may result in decreased hydromorphone absorption with JURNISTA and may potentially lead to withdrawal symptoms in patients with a physical dependence on opioids.

The administration of opioids may obscure the diagnosis or clinical course of acute abdominal conditions. Therefore it is important to make sure that the patient is not suffering from intestinal occlusion, especially of the ileus, before initiation of treatment. Hydromorphone also can cause an increase in biliary tract pressure as a result of spasm in the sphincter of Oddi. Caution should therefore be exercised in the administration of JURNISTA to patients with inflammatory or obstructive bowel disorders, acute pancreatitis secondary to biliary tract disease and in patients about to undergo biliary surgery.

The JURNISTA tablet is nondeformable and does not appreciably change in shape in the gastrointestinal tract. There have been very rare reports of obstructive symptoms in patients with known strictures in association with ingestion of medicinal products in nondeformable controlled-release formulations (see *Contraindications*).

Patients should be advised not to be alarmed if they notice what appears to be the JURNISTA tablet in their stools, as it is simply the non-dissolvable shell.

Special risk patients
JURNISTA, like all opioid analgesics, should be administered with caution and in reduced dosages in patients with renal insufficiency or mild to moderate hepatic insufficiency, adrenocortical insufficiency, myxedema, hypothyroidism, prostatic hypertrophy or urethral stricture. Caution should also be exercised in the administration of JURNISTA to patients with central nervous system depression, kyphoscoliosis, toxic psychosis, acute alcoholism, delirium tremens, or convulsive disorders.

JURNISTA should not be used during breast-feeding.

Use in renal and hepatic impairment
Patients with either moderate hepatic or renal insufficiency should be started on a reduced dose and closely monitored during dose titration. In patients with severe renal insufficiency an increased dosing interval should also be considered and these patients should in addition be monitored during maintenance therapy for development of opioid-related adverse reactions (see *Dosage and Administration – Special populations*).

Use in the elderly
Elderly patients are more prone to central nervous system adverse effects (confusion) and gastrointestinal disturbances, and physiological reduction of renal function. Therefore, extra caution should be shown, and the initial dose should be reduced. Concomitant use of other medications, especially tricyclic antidepressants, increases the risk of confusion and constipation. Diseases of the prostate gland and the urinary tract are often seen in the elderly. This contributes to the increased risk of urinary retention. The above considerations emphasize the importance of caution rather than imply a restriction on the use of opioids in the elderly.

Drug dependence and substance abuse and use with alcohol
Physical dependence is a state of adaptation that is manifested by an opioid specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

The opioid abstinence or withdrawal syndrome is characterized by some or all of the following: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, piloerection, myalgia, mydriasis, irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate.

In general, opioids should not be abruptly discontinued (see *Dosage and Administration – Stopping treatment*).

Do not abruptly discontinue JURNISTA in a patient physically dependent on opioids. There have been reports that rapid tapering of JURNISTA in a patient physically dependent on opioids may lead to serious withdrawal symptoms and uncontrolled pain (see *Dosage and Administration, Stopping Treatment*).

JURNISTA should be used with caution in patients with alcoholism and other drug dependencies due to the increased frequency of opioid tolerance and psychological dependence observed in these patient populations. With abuse by parenteral routes, the tablet excipients may cause lethal complications.

Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression).

Opioid induced hyperalgesia
Opioid induced hyperalgesia (OIH) is a paradoxical response to an opioid in which there is an increase in pain perception despite stable or increased opioid exposure. It differs from tolerance, in which higher opioid doses are required to achieve the same analgesic effect or treat recurring pain. OIH may manifest as increased levels of pain, more generalized pain (i.e., less focal), or pain from ordinary (i.e. non-painful) stimuli (allodynia) with no evidence of disease progression. When OIH is suspected, the dose of opioid should be reduced or tapered off, if possible.

Lactose
JURNISTA contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp deficiency or glucose-galactose malabsorption should not take this medicine.

Sulfite allergy
JURNISTA may contain sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Misuse, Abuse and Diversion
Hydromorphone is an opioid agonist of the morphine-type. Such drugs are sought by drug abusers and people with addiction disorders and are subjects to criminal diversion. JURNISTA can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing JURNISTA in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Prescribers should monitor all patients receiving opioids for signs of abuse, misuse and addiction. Furthermore, patients should be assessed for their potential for opioid abuse prior to being prescribed opioid therapy. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse) or mental illness (e.g. depression). Opioids may still be appropriate for use in these patients, however, they will require intensive monitoring for signs of abuse. Concerns about abuse, addiction, and diversion should not prevent the proper management of pain.

INTERACTIONS
Based on its pharmacodynamic and pharmacokinetic properties, hydromorphone exhibits a potential for pharmacodynamic interactions. The various types of interaction, associated general recommendations, and lists of examples are described below. These lists of examples are not comprehensive and therefore it is recommended that the label of each drug that is coadministered with hydromorphone be consulted for information related to interaction pathways, potential risks, and specific actions to be taken with regards to coadministration.

Central Nervous System (CNS) depressants, including alcohol and some illegal drugs	
Clinical Impact	Due to additive pharmacodynamic effects, the concomitant use of JURNISTA with central nervous system depressants may disproportionately increase the CNS depressant effects and respiratory depression. Additionally, hypotension and profound sedation, coma or death may occur.
Intervention	When this combination is indicated, the dose of one or both agents should be reduced.
Examples	Other central nervous system depressants, including benzodiazepines and other hypnotics/sedatives, general anesthetics, antipsychotics, and alcohol and some illegal drugs.
Monoamine Oxidase Inhibitors (MAOI)	
Clinical Impact	Due to additive pharmacodynamic effects, Monoamine oxidase inhibitors (MAOIs) may cause central nervous system excitation or depression, hypotension or hypertension if co-administered with opioids.
Intervention	JURNISTA is not intended for patients taking MAOIs or within 14 days of stopping such treatment.
Morphine agonists/antagonists	
Clinical Impact	The concomitant use of hydromorphone with morphine agonists/antagonists could lead to a reduction of the analgesic effect by competitive blocking of

	receptors, thus leading to risk of withdrawal symptoms.
Intervention	The combination of hydromorphone and morphine agonists/antagonists is not recommended.
Examples	buprenorphine, nalbuphine, pentazocine
Muscle Relaxants	
Clinical Impact	JURNISTA, like other opioids, may enhance the neuromuscular blocking action of muscle relaxants and cause an increased degree of respiratory depression.

Pregnancy and Breast-feeding
Pregnancy
No clinical data on exposed pregnancies are available. While studies in rats and rabbits revealed no teratogenic effects, reproductive toxicity has been observed (see *Non-Clinical Information*). Hydromorphone has been shown to cross the placental barrier in experimental animals. The potential teratogenic risk for humans from use of hydromorphone and other opioids during pregnancy is unknown.

JURNISTA should not be used during pregnancy and labor due to impaired uterine contractility and the risk of neonatal respiratory depression. Withdrawal symptoms may be observed in the newborn of mothers undergoing chronic treatment.

Breast-feeding
Low concentrations of hydromorphone and other opioid analgesics have been detected in human milk in clinical studies. Preclinical studies have shown that hydromorphone can be detected in milk of lactating rats. JURNISTA should not be used during breast-feeding.

Effects on Ability to Drive and Use Machines
JURNISTA can have a major influence on the ability to drive and use machines. This is particularly likely at the start of therapy, following an increase in dose or change of preparation.

ADVERSE REACTIONS
Throughout this section, adverse reactions are presented. Adverse reactions are adverse events that were considered to be reasonably associated with the use of hydromorphone hydrochloride based on the comprehensive assessment of the available adverse event information. A causal relationship with hydromorphone hydrochloride cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Clinical Trial Data
Placebo-controlled double-blind data – adverse reactions reported at ≥1% incidence
The safety of JURNISTA was evaluated in 788 patients who participated in 2 multicenter, double-blind, randomized, placebo-controlled clinical trials in patients with osteoarthritis, who received at least one dose of JURNISTA (Studies M03-644-05 and 42801PAI3001) and provided safety data. The drug titration phases lasted up to 4 weeks, and maintenance phases were 12 weeks at doses of 8 to 32 mg/day; Study M03-644-05 also included a taper phase of up to 1 week. Adverse reactions reported for ≥1% of JURNISTA -treated patients and with an incidence greater than placebo-treated patients are shown in Table 2.

Table 2. Adverse Reactions Reported by ≥1% of JURNISTA -Treated Patient and with an Incidence Greater than Placebo-Treated Patients in 2 Double-Blind, Placebo-Controlled Clinical Trials of JURNISTA

System Organ Class Adverse Reaction	**JURNISTA** **%** **(N=788)**	**Placebo** **%** **(N=481)**
Infections and infestations		
Gastroenteritis	2.2	0.6
Metabolism and nutrition disorders		
Decreased appetite	4.6	0.8
Psychiatric disorders		
Insomnia	4.3	2.5
Anxiety	2.2	0.8
Depression	1.6	0.2
Nervousness	1.4	0.2
Confusional state	1.3	0
Abnormal dreams	1.0	0
Libido decreased	1.0	0
Nervous system disorders		
Somnolence	18.7	7.9
Dizziness	12.3	5.2
Headache	11.7	8.9
Paraesthesia	1.1	0.8
Tremor	1.0	0.4
Ear and labyrinth disorders		
Vertigo	2.5	1.2
Cardiac disorders		
Palpitations	1.1	0.2
Vascular disorders		
Flushing	1.0	0.4
Respiratory, thoracic and mediastinal disorders		
Dyspnoea	1.3	0.4
Gastrointestinal disorders		
Constipation	44.4	11.0
Nausea	32.7	8.7
Vomiting	10.4	1.9
Diarrhoea	6.9	6.7
Dry mouth	6.1	3.3
Abdominal pain	5.7	2.7
Dyspepsia	2.4	2.1
Flatulence	1.4	0.8
Skin and subcutaneous tissue disorders		
Pruritus	10.8	1.9
Hyperhidrosis	3.2	0
Rash	1.8	1.0
Musculoskeletal and connective tissue disorders		
Arthralgia	2.5	1.7
General disorders and administration site conditions		
Asthenia	9.1	2.9
Oedema	2.4	1.7
Pyrexia	1.3	0.4
Chest discomfort	1.1	0.8
Investigations		
Weight decreased	1.3	0.2
Injury, poisoning and procedural complications		
Fall	1.6	1.2
Contusion	1.1	0.6

Comparator-controlled and extension study data – adverse reactions reported at ≥1% incidence

Adverse reactions not reported in Table 2 that were reported by ≥1% of JURNISTA -treated patients (N=2340) in 11 clinical trials (including the 2 placebo-controlled trials presented in Table 3) and 3 extension studies of JURNISTA in the treatment of chronic malignant or nonmalignant pain are shown in Table 3. All patients received at least one dose of JURNISTA and provided safety data.

Table 3. Adverse Reactions Reported by ≥1% of JURNISTA -Treated Patients in 11 Clinical Trials and 3 Extension Studies of JURNISTA	
System Organ Class Adverse Reaction	**JURNISTA %** **(N=2340)**
Metabolism and nutrition disorders	
Dehydration	1.5
Psychiatric disorders	
Restlessness	1.7
Mood altered	1.2
Hallucination	1.1
Nervous system disorders	
Sedation	1.7
Hypoaesthesia	1.6
Memory impairment	1.2
Eye disorders	
Vision blurred	1.9
Vascular disorders	
Hypertension	2.2
Gastrointestinal disorders	
Oesophageal reflux aggravated	1.2
Musculoskeletal and connective tissue disorders	
Back pain	3.9
Muscle spasms	3.8
Pain in extremity	2.7
Myalgia	1.0
Renal and urinary disorders	
Dysuria	1.3
General disorders and administration site conditions	
Pain	2.5
Drug withdrawal syndrome	2.2
Chills	1.2

Comparator-controlled and extension study data – adverse reactions reported at <1% incidence

Adverse reactions reported by <1% of JURNISTA -treated patients (N=2340) in the above clinical trial dataset are shown in Table 4.

Table 4. Adverse Reactions Reported by <1% of JURNISTA -Treated Patients in 11 Clinical Trials and 3 Extension Studies of JURNISTA

System Organ Class Adverse Reaction	JURNISTA % (N=2340)
Infections and infestations	
Diverticulitis	0.21
Endocrine disorders	
Hypogonadism	0.04
Metabolism and nutrition disorders	
Fluid retention	0.30
Increased appetite	0.30
Hyperuricaemia	0.09
Psychiatric disorders	
Sleep disorder	0.64
Panic attack	0.34
Dysphoria	0.17
Paranoia	0.17
Euphoric mood	0.13
Listless	0.13
Aggression	0.09
Nervous system disorders	
Dysgeusia	0.94
Disturbance in attention	0.85
Dysarthria	0.64
Syncope	0.64
Depressed level of consciousness	0.43
Balance disorder	0.43
Coordination abnormal	0.38
Hyperaesthesia	0.26
Myoclonus	0.26
Dyskinesia	0.21
Crying	0.13
Encephalopathy	0.13
Psychomotor hyperactivity	0.09
Cognitive disorder	0.09
Convulsion	0.09
Hyperreflexia	0.04
Eye disorders	
Diplopia	0.34
Dry eye	0.26
Miosis	0.04
Ear and labyrinth disorders	
Tinnitus	0.81
Cardiac disorders	
Tachycardia	0.81
Extrasystoles	0.17
Bradycardia	0.09
Vascular disorders	
Hypotension	0.68
Respiratory, thoracic and mediastinal disorders	
Rhinorrhoea	0.51
Respiratory distress	0.26
Bronchospasm	0.17
Hypoxia	0.17
Respiratory depression	0.13
Hyperventilation	0.09
Sneezing	0.09
Gastrointestinal disorders	
Dysphagia	0.77
Haematochezia	0.64
Abdominal distension	0.43
Haemorrhoids	0.38
Abnormal faeces	0.30
Intestinal obstruction	0.21
Diverticulum	0.13
Eructation	0.13
Gastrointestinal motility disorder	0.13
Ileus	0.09
Large intestine perforation	0.09
Anal fissure	0.04
Bezoar	0.04
Duodenitis	0.04
Impaired gastric emptying	0.04
Painful defaecation	0.04

Table 4. Adverse Reactions Reported by <1% of JURNISTA -Treated Patients in 11 Clinical Trials and 3 Extension Studies of JURNISTA

System Organ Class Adverse Reaction	JURNISTA % (N=2340)
Skin and subcutaneous tissue disorders	
Erythema	0.43
Skin burning sensation	0.04
Renal and urinary disorders	
Urinary retention	0.90
Pollakiuria	0.77
Urinary hesitation	0.64
Micturition disorder	0.38
Reproductive system and breast disorders	
Erectile dysfunction	0.60
Sexual dysfunction	0.43
General disorders and administration site conditions	
Influenza like illness	0.85
Malaise	0.77
Feeling of body temperature change	0.60
Feeling abnormal	0.38
Feeling jittery	0.30
Gait disturbance	0.17
Hangover	0.09
Feeling drunk	0.04
Investigations	
Blood potassium decreased	0.98
Hepatic enzyme increased	0.30
Blood amylase increased	0.09
Blood testosterone decreased	0.04
Body temperature decreased	0.04
Injury, poisoning and procedural complications	
Overdose	0.30

Postmarketing data

In addition to the adverse reactions reported during clinical studies and listed above, the following adverse reactions have been reported during postmarketing experience (Tables 5 and 6). In each table, the frequencies are provided according to the following convention:

Very common	≥ 1/10
Common	≥ 1/100 and < 1/10
Uncommon	≥ 1/ 1000 and < 1/100
Rare	≥ 1/10000 and < 1/1000
Very rare	< 1/10000, including isolated reports.

In Table 5, adverse reactions are presented by frequency category based on spontaneous reporting rates, while in Table 6, the same adverse reactions are presented by frequency category based on incidence in clinical trials or epidemiology studies, when known.

Table 5. Adverse Reactions Identified During Postmarketing Experience with JURNISTA by Frequency Category Estimated from Spontaneous Reporting Rates

System Organ Class Adverse Reaction	
Immune System Disorders	
Very rare	Hypersensitivity
Skin and subcutaneous disorders	
Very rare	Angioedema, Urticaria
Nervous System Disorders	
Very rare	Sleep apnea syndromes

Table 6. Adverse Reactions Identified During Postmarketing Experience with JURNISTA by Frequency Category Estimated from Clinical Trials

System Organ Class Adverse Reaction	
Immune System Disorders	
Uncommon	Hypersensitivity
Skin and subcutaneous disorders	
Uncommon	Angioedema, Urticaria
Nervous System Disorders	
Not known	Sleep apnea syndromes

Overdose

Symptoms and signs

Opioid overdose is characterized by respiratory depression, drowsiness which progresses to stupor and coma, musculoskeletal flaccidity, cold skin, contracted pupils and, at times, tachycardia and hypotension. In cases of severe overdose, apnoea, circulatory collapse, cardiac arrest and death may occur.

Treatment

In the treatment of overdose, primary attention should be given to the reestablishment of adequate respiratory exchange keeping the airway open and instituting assisted or controlled ventilation.

Supportive measures (including oxygen and vasopressors) should be used to manage the shock and pulmonary edema which potentially accompany overdose. Cardiac arrest and arrhythmias may require cardiac massage or defibrillation.

In cases of severe overdose, specific antidotes such as naloxone and nalmefene should be used to manage respiratory depression (see the prescribing information for the specific opioid antagonist for details of proper use). The effect of naloxone is relatively short; therefore, the patient should be carefully monitored until respiration has stabilized. JURNISTA will release hydromorphone for approximately 24 hours. This should be taken into account in determining the treatment. Opioid antagonists should not be given in the absence of clinically significant respiratory depression or circulatory depression caused by opioids. Opioid antagonists should be administered with caution to patients suspected to be physically dependent on hydromorphone, since rapid reversal of an opioid, including hydromorphone, may precipitate symptoms of withdrawal.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Pharmacotherapeutic group: Analgesics; natural opium alkaloids, ATC code: N02AA03. Hydromorphone is a semisynthetic morphine derivative.

Mechanism of action

As with all opioid analgesics, hydromorphone exerts its principal pharmacological effects on the central nervous system and smooth muscle, including the gastrointestinal tract. These effects are expressed and modulated by binding to specific opioid receptors. Hydromorphone is principally an agonist of μ-receptors, showing a weak affinity for κ-receptors. Analgesia occurs as a consequence of the binding of hydromorphone to the μ-receptors of the central nervous system. Although estimates vary (from 2 to 10 times), oral hydromorphone appears to be approximately 5 times as potent (by weight) as morphine.

Pharmacodynamic effects

Respiratory depression occurs principally by direct action on the cerebral respiratory control centers. Opioids may cause nausea and vomiting due to direct stimulation of the chemoreceptors for emesis in the posterior area of the medulla.

Pharmacokinetic Properties

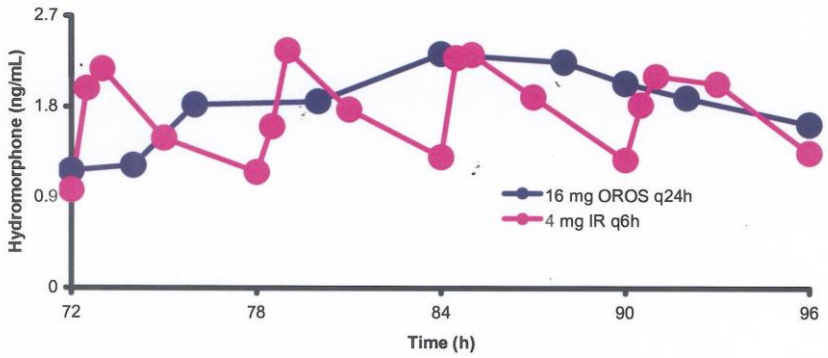
Absorption

Following a single oral dose of JURNISTA extended-release tablets, plasma concentrations gradually increase over 6 to 8 hours and thereafter concentrations are sustained for approximately 18 to 24 hours post-dose; the mean Tmax values were approximately 13 to 16 hours. This demonstrates that, as intended, hydromorphone is released in a controlled manner from the dosage form, with drug absorption continuing throughout the intestinal tract for approximately 24 hours, consistent with once-daily dosing. The mean absolute bioavailability of hydromorphone after a single dose of 8, 16 or 32 mg of JURNISTA ranged from 22% to 26%. The concomitant administration of JURNISTA with a high fat meal has no effect on the absorption of hydromorphone.

Steady state plasma concentrations are approximately twice those observed following the first dose, and steady state is reached by the fourth dose of JURNISTA. No time dependent change in pharmacokinetics was seen with multiple dosing. At steady state, JURNISTA given once daily maintained hydromorphone plasma concentrations within the same concentration range as the immediate-release tablet given 4-times daily at the same total daily dose and

diminishes the periodic fluctuations in plasma levels seen with the immediate-release tablet. The degree of fluctuation in plasma concentration at steady state during a 24-hour period [(calculated as ($C_{max(ss)} - C_{min(ss)}/C_{avg(ss)}$) x 100%)] was lower with JURNISTA (83%) as compared to the overall fluctuations of the immediate-release tablet (147%) (see Figure 1). At steady state, hydromorphone AUC for JURNISTA is equivalent to that observed for the immediate-release tablet.

Figure 1. Steady-State Plasma Concentration Profile (n = 18 naltrexone blocked healthy subjects)



Linear pharmacokinetics has been demonstrated for the extended-release tablet over the dose range 4 to 64 mg, with dose proportional increases in plasma concentrations (Cmax) and overall exposure (AUC).

Distribution
Plasma protein binding is low (<30%).

Metabolism
Glucuronidation is the main metabolic pathway and the principal metabolite is the inactive hydromorphone 3-glucuronide, which follows a similar time course to hydromorphone in plasma. Unlike morphine, no active 6-glucuronide metabolite is produced.

Special populations
Elderly
The effect of age on the single-dose pharmacokinetics of hydromorphone immediate-release resulted in a 14% decrease in Cmax and a modest increase (11%) in AUC in the elderly compared to the young. No difference in Tmax was observed. These effects are considered unlikely to be clinically relevant. Greater sensitivity of older individuals cannot be excluded. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in this population.

Renal impairment
Renal impairment affected the pharmacokinetics of hydromorphone and its metabolite hydromorphone 3-glucuronide following administration of a single oral dose of the immediate-release tablet. The effects of renal impairment on hydromorphone pharmacokinetics were two-fold and four-fold increases in hydromorphone bioavailability in moderate and severe impairment, respectively. There were also substantial changes in hydromorphone 3-glucuronide elimination kinetics for the severe impairment group, although hemodialysis was effective at reducing plasma levels of both hydromorphone and metabolites. See *Dosage and Administration – Special populations* for recommendations on dosage.

Hepatic impairment
In studies that used single oral dosing with conventional (immediate-release) tablets, hepatic impairment reduces the first-pass metabolism of hydromorphone such that four-fold higher plasma levels of hydromorphone are seen in subjects with moderate hepatic dysfunction. See *Dosage and Administration – Special populations* for recommendations on dosage.

Gender
Hydromorphone plasma concentrations and pharmacokinetic parameters following administration of JURNISTA are comparable in male and female subjects.

Alcohol

In a study evaluating hydromorphone absorption from JURNISTA when taken with 240 mL of 4%, 20% and 40% alcohol, Cmax increased on average by 17, 31, and 28% respectively in the fasting state and was less affected in the fed state with increases of 14, 14, and 10%, respectively. Median Tmax (fasted and fed) with 4, 20 and 40% alcohol was 12 to 16 h and with 0% alcohol was 16 h. No effect was seen on AUC values both in the fed and fasted state. Concomitant use of alcohol should be avoided (see *Warnings and Precautions*). Due to the OROS® technology in JURNISTA, the extended-release properties of JURNISTA are maintained in the presence of alcohol. For the pharmacodynamic interactions, see *Warnings and Precautions*.

NON-CLINICAL INFORMATION
Non-clinical data from oral administration of hydromorphone reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity and fertility. The major effects were opioid-related pharmacological activities on the central nervous system and gastrointestinal tract, including dose-related increases in sedation, hyperactivity, sudden death, weight loss and decrease in food consumption.

Carcinogenicity
Long-term studies of hydromorphone showed no evidence of any carcinogenic effects after daily oral dosing for two years in mice and rats. The steady state plasma exposure (AUC, ng·hr/mL) to hydromorphone in mice was approximately 0.46-times and in rats was greater than 3-times the human exposure following a single 64 mg dose of JURNISTA.

Reproductive Toxicology
In the rat, a slight but statistically significant reduction in implantations was observed at 6.25 mg/kg/day, a dose level that produced maternal toxicity during the mating period. Plasma exposure (AUC) to hydromorphone at this dose level was 135 ng·hr/mL, providing a safety factor of about 1.5 over the human exposure (AUC) based on the median daily dose. Neonatal viability and survival were reduced in rats pre-weaning, at the maternal oral daily dose of 6.25 mg/kg. The latter appears to be a class effect of an opioid analgesic.

PHARMACEUTICAL PARTICULARS
List of Excipients
Butyl hydroxytoluene E321
Cellulose acetate
Glycerol triacetate
Iron oxide black E172
Hypromellose
Lactose
Macrogol
Magnesium stearate
Polyethylene oxide
Povidone
Propylene glycol
Sodium chloride
Titanium dioxide E171
Ferric oxide yellow E172 (32mg only)
Ferric oxide yellow E172 (16 mg and 32 mg only)
Indigo carmine lake E132 (64 mg only)

Incompatibilities
Not applicable.

Shelf Life
2 years

Special Precautions for Storage
Store below 30°C.
Keep out of the sight and reach of children.

Because of the risks associated with accidental ingestion, misuse, and abuse, advise patients to store JURNISTA securely, in a location not accessible by others.

Instructions for Use and Handling and Disposal
Any unused JURNISTA should be disposed of in accordance with local requirements.

HOW SUPPLIED
JURNISTA 8 mg prolonged-release tablets
Box @ 4 blister @ 7 tablets
Reg. No.: DNI1310900714B1

JURNISTA 16 mg prolonged-release tablets
Box @ 4 blister @ 7 tablets
Reg. No.: DNI1310900714C1

HARUS DENGAN RESEP DOKTER

Manufactured by ALZA Corporation, Vacaville, USA
Released by Janssen-Cilag S.p.A., Latina, Italy
Imported and distributed by PT Kimia Farma (Persero) Tbk, Jl. Veteran No. 9, Jakarta 10110, Indonesia – (021) 384-7709
For adverse event and product quality complaint, please contact: drugsafety@jacid.jnj.com or (021) 2935-3935

Based on CCDS 11 July 2019 ver.009+17 April 2020 ver.010

INFORMASI PRODUK UNTUK PASIEN

JURNISTA 16mg, 32 mg tablet pelepasan lambat
Hidromorfon hidroklorida

Baca semua informasi produk ini secara seksama sebelum Anda mulai menggunakan obat ini.
- Simpan informasi produk ini. Anda mungkin perlu untuk membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Obat ini hanya diresepkan untuk Anda. Jangan memberikannya ke orang lain. Hal ini dapat membahayakan orang lain, bahkan jika tanda-tanda penyakit mereka sama seperti penyakit Anda.

Apa yang ada dalam informasi produk ini

1. Apakah JURNISTA dan apa kegunaannya

JURNISTA mengandung zat aktif hidromorfon hidroklorida. Zat aktif ini termasuk ke dalam kelompok obat yang disebut ‘analgesik opioid” (pereda nyeri golongan morfin)

JURNISTA digunakan untuk mengobati nyeri sedang sampai berat pada orang dewasa yang membutuhkan pereda nyeri secara berkelanjutan.

2. Apa saja yang perlu Anda ketahui sebelum menggunakan JURNISTA

Jangan menggunakan JURNISTA:
- jika Anda alergi terhadap hidromorfon hidroklorida atau salah satu bahan lain dari obat ini (tercantum dalam bagian 6). Lihat 'Perhatikan efek samping yang serius' di bagian 4, untuk tanda-tanda reaksi alergi.
- jika Anda didiagnosis mengalami penyempitan atau penyumbatan lambung dan/atau usus (usus) yang serius
- jika Anda pernah melakukan operasi yang meninggalkan tanda ‘blind loops’ di usus Anda
- untuk mengobati nyeri akut, atau nyeri setelah operasi
- jika Anda menderita asma akut berat.
- jika Anda memiliki kesulitan bernapas yang serius, dengan napas yang lambat atau pendek

Beritahu dokter Anda jika ini hal ini terjadi pada Anda.

JURNISTA tidak boleh digunakan untuk anak-anak di bawah umur 18 tahun, atau wanita hamil, dalam persalinan atau saat melahirkan.

Peringatan dan perhatian
Bicarakan dengan dokter atau apoteker Anda sebelum menggunakan JURNISTA. Beberapa orang perlu berhati-hati ketika mereka menggunakan obat ini.

Efek samping yang serius
JURNISTA dapat menyebabkan efek samping yang serius, termasuk kesulitan bernapas dan reaksi alergi. Anda harus menyadari efek samping ini, atau mencari tanda-tanda penyakit tertentu saat Anda menggunakan JURNISTA. Lihat 'Perhatikan efek samping yang serius' di bagian 4.

Periksakan dengan dokter Anda jika Anda memiliki, atau baru saja memiliki, salah satu dari hal berikut:
- kesulitan bernafas atau masalah dengan paru-paru Anda, termasuk penyakit paru obstruktif kronik (PPOK)
- JURNISTA menyebabkan penurunan kadar oksigen dalam darah dan gangguan *sleep apnea* (berhenti bernapas pada waktu tertentu saat tidur). Beritahu dokter Anda jika Anda memiliki riwayat gangguan *sleep apnea* atau jika orang lain menyadari bahwa Anda berhenti bernapas pada waktu tertentu saat tidur.

DISETUJUI OLEH BPOM : 01/11/2020

ID : EREG10030312000201, EREG10030312000202
EREG10030312000199, EREG10030312000200

- pengobatan dengan pereda nyeri golongan morfin lainnya
- sakit kepala atau cedera kepala
- konstipasi kronis
- diare berat yang muncul tiba-tiba
- penyakit apa pun di usus Anda, termasuk obstruksi atau penyakit radang usus (IBD)
- pankreatitis (radang pankreas) atau penyakit pada saluran empedu
- masalah dengan ginjal, hati, jantung atau kelenjar adrenal
- tiroid yang kurang aktif (hipotiroidisme)
- pembesaran prostat
- kesulitan buang air kecil
- jika Anda atau keluarga Anda memiliki riwayat ketergantungan obat atau penyalahgunaan obat-obatan, alkohol, atau obat penghilang rasa sakit golongan opioid
- jika Anda memiliki reaksi yang parah saat menghentikan alkohol (kadang disebut delirium tremens)
- Depresi sistem saraf pusat (SSP) - tanda-tanda ini termasuk rasa kantuk yang berat, suhu tubuh yang rendah dan kadang-kadang koma
- sawan atau kejang (epilepsi atau kejang)
- psikosis toksik (kebingungan ekstrim)
- kyphoscoliosis (kelengkungan abnormal pada tulang belakang).

Beritahu dokter Anda:
- jika Anda akan menjalani chordotomy atau operasi serupa untuk meredakan rasa sakit Anda. Anda tidak boleh menggunakan JURNISTA sesaat sebelum atau segera setelah operasi, dokter akan memberi tahu Anda kapan harus berhenti menggunakan JURNISTA dan kapan Anda dapat mulai menggunakannya lagi, atau jika dosis Anda perlu diubah.
- jika Anda berusia lebih dari 60 tahun. Anda lebih mungkin mengalami efek samping, sehingga dokter Anda mungkin memberi Anda dosis awal yang rendah.

Penggunaan dengan penekan sistem saraf pusat, termasuk alkohol dan beberapa obat-obatan terlarang
Beritahu dokter Anda jika Anda mengonsumsi obat-obat lain yang memperlambat sistem saraf pusat Anda (misalnya, obat-obatan yang membuat Anda mengantuk, mengurangi kecemasan atau mengurangi kesadaran). Menggunakan obat-obatan jenis ini (penekan SSP), termasuk alkohol dan beberapa obat terlarang, dengan JURNISTA dapat menyebabkan kantuk yang berat, kesadaran menurun, kesulitan bernapas dengan pernapasan lambat atau dangkal, koma dan kematian.

Sembelit
Sembelit (susah buang air besar) adalah efek samping yang umum dari obat seperti JURNISTA dan kecil kemungkinan dapat hilang tanpa pengobatan. Bicaralah dengan dokter atau apoteker Anda tentang penggunaan laksatif (obat-obatan untuk mengobati sembelit) dan pelunak feses untuk mencegah atau mengobati sembelit saat menggunakan JURNISTA.

Ketika Anda ke toilet
Anda mungkin melihat benda seperti tablet JURNISTA di tinja Anda. Jangan khawatir - ini hanyalah cangkang tablet, yang tidak melewati tubuh Anda tanpa mengalami perubahan. Itu tidak berarti tablet tidak berfungsi.

Obat-obatan lainnya dan JURNISTA
Beberapa obat dapat memengaruhi cara kerja JURNISTA, atau dapat meningkatkan kemungkinan Anda mengalami efek samping.

Jangan menggunakan JURNISTA jika Anda menggunakan:
- antidepresan yang disebut monoamine oxidase inhibitors (MAOIs), atau telah meminumnya dalam 14 hari terakhir
- obat pereda rasa sakit lainnya yang termasuk golongan morfin (buprenorfin, nalbuphine atau pentazocine).

Beritahu dokter Anda jika hal ini berlaku pada Anda.

Periksakan dengan dokter Anda sebelum menggunakan JURNISTA jika Anda mengunakan atau pernah menerima:
- obat-obatan yang memperlambat sistem saraf pusat Anda (penekan SSP) seperti obat penenang, obat tidur, obat-obatan yang digunakan untuk pembedahan (anestesi), penenang, obat-obatan untuk gangguan mental (antipsikotik), alkohol, atau obat-obatan terlarang.

- relaksan otot (ini mungkin diresepkan untuk nyeri punggung).

Beritahu kepada dokter atau apoteker Anda jika Anda baru saja menggunakan, atau mungkin menggunakan obat-obatan lain.

JURNISTA dengan alkohol
Minum alkohol saat menggunakan JURNISTA dapat membuat Anda merasa lebih mengantuk atau meningkatkan risiko efek samping yang serius, seperti pernapasan yang pendek, dengan risiko pernapasan berhenti dan kehilangan kesadaran. Dianjurkan untuk tidak minum alkohol saat Anda menggunakan JURNISTA.

Kehamilan dan menyusui
JURNISTA tidak disarankan untuk digunakan selama kehamilan. Bicarakan dengan dokter Anda jika Anda hamil, merasa hamil atau berencana untuk memiliki bayi. JURNISTA tidak disarankan untuk digunakan selama proses melahirkan dikarenakan obat ini dapat memperlambat napas bayi yang baru dilahirkan. Penggunakan JURNISTA jangka panjang selama kehamilan dapat menyebabkan gejala putus obat pada bayi yang baru dilahirkan yang dapat membahayakan jiwa jika tidak diketahui dan ditangani.

Jangan menggunakan JURNISTA jika Anda sedang menyusui, karena bahan aktifnya dapat masuk ke dalam ASI.

Perubahan rasa sakit yang Anda rasakan
Beritahu dokter Anda jika:
- Anda merasakan rasa sakit yang Anda alami tidak lagi dapat diredakan oleh Jurnista
- Anda merasakan peningkatan rasa sakit
- Ada perubahan dalam bagaimana Anda merasakan rasa sakit yang Anda alami (misalnya, Anda merasakan sakit di bagian lain dari tubuh Anda)
- Anda merasakan sakit ketika sesuatu menyentuh tubuh Anda yang secara tidak diduga dapat menyakiti Anda.

Jangan mengubah dosis sendiri. Dokter Anda mungkin memutuskan untuk mengubah dosis atau pengobatan Anda.

Mengemudi dan menggunakan mesin
JURNISTA dapat membuat Anda mengantuk. Jangan mengemudikan kendaraan, mengoperasikan mesin, atau melakukan pekerjaan berbahaya sampai Anda yakin Anda tidak terpengaruh. Berhati-hatilah jika dosis atau jenis obat Anda berubah.

Tablet salut JURNISTA mengandung laktosa
Jika Anda telah diberitahu oleh dokter Anda bahwa Anda memiliki intoleransi terhadap beberapa gula, hubungi dokter Anda sebelum menggunakan obat ini.

Tablet salut JURNISTA mungkin mengandung natrium metabisulfit
Hal ini dapat menyebabkan reaksi alergi atau serangan asma yang parah, terutama pada penderita asma. Lihat 'Perhatikan efek samping yang serius' di bagian 4, untuk tanda-tanda reaksi alergi.

3. Bagaimana cara menggunakan JURNISTA

Selalu gunakan obat ini sama seperti yang dikatakan oleh dokter atau perawat Anda. Tanyakan kepada dokter, perawat, atau apoteker Anda jika Anda tidak yakin. Dosis efektif terendah harus digunakan dalam durasi waktu yang paling singkat.

Jika Anda tidak secara rutin mengonsumsi obat pereda rasa sakit golongan morfin, dosis awal JURNISTA yang biasa adalah 8 mg setiap hari. Jika Anda mengganti obat pereda rasa sakit dari golongan morfin yang berbeda, dokter Anda mungkin akan meresepkan dosis awal JURNISTA yang berbeda.

Dokter Anda dapat menaikkan dosis sampai rasa sakit Anda terkontrol, dengan rentang waktu setidaknya tiga hari diantara kenaikan dosis (misalnya, jika dosis pertama Anda pada hari Senin, peningkatan dosis dilakukan pada hari Kamis).

Penggunaan tablet harian Anda

Telan tablet JURNISTA secara utuh, dengan segelas air.
JURNISTA merupakan sediaan tablet yang larut secara perlahan, yang berarti bahwa zat aktif secara bertahap dilepaskan ke dalam tubuh setelah diminum.
Jangan mengunyah, menghancurkan atau mematahkan tablet JURNISTA - jika Anda melakukannya, bahayanya adalah Anda bisa overdosis, karena obat akan dilepaskan ke tubuh Anda terlalu cepat.

Jangan menghancurkan dan menyuntikkan tablet, karena beberapa bahan berpotensi menyebabkan kematian jika digunakan dengan cara ini.

Cobalah untuk meminum JURNISTA pada waktu yang sama setiap hari. Anda dapat meminum obat ini dengan atau tanpa makanan.

Jika Anda meminum JURNISTA lebih dari yang seharusnya
Segera hubungi dokter Anda atau unit gawat darurat rumah sakit terdekat. Jika memungkinkan, beri tahu mereka tablet apa yang telah Anda minum, dan berapa banyak.

Jika Anda mengalami overdosis, Anda mungkin merasa sangat mengantuk dan mengalami kesulitan bernapas. Efek overdosis bisa memburuk - termasuk kulit berkerut, pupil mengecil, tekanan darah rendah dan koma (tidak sadar). Seseorang yang mengalami overdosis yang serius dapat menyebabkan henti napas, mengalami serangan jantung, dan meninggal.

Jika Anda lupa meminum JURNISTA
Minumlah dosis berikutnya segera setelah Anda ingat, dan kemudian pada waktu yang sama setiap hari. **Jangan meminum tablet tambahan atau dosis ganda untuk mengganti tablet yang terlupakan.** Hubungi dokter atau apoteker Anda jika Anda tidak yakin dengan apa yang harus dilakukan.

Jika Anda berhenti menggunakan JURNISTA
Jika tiba waktunya bagi Anda untuk berhenti menggunakan JURNISTA, dokter Anda akan mengurangi dosis Anda secara bertahap - biasanya dengan mengurangi separuh dosis setiap dua hari. Setelah mencapai dosis serendah mungkin, dokter akan berdiskusi dengan Anda kapan Anda dapat berhenti menggunakan JURNISTA.

Beberapa orang mendapatkan gejala ketika dosis JURNISTA tiba-tiba berkurang, atau jika pengobatan tiba-tiba berhenti. Gejala-gejala ini termasuk:
- kecemasan atau iritabilitas
- pupil besar (membesar)
- pipi memerah atau berkeringat
- menangis tanpa alasan
- mual, muntah atau diare
- sakit perut atau nyeri sendi.

Beritahu dokter Anda jika Anda mendapatkan gejala-gejala ini setelah Anda berhenti menggunakan JURNISTA atau jika dosis JURNISTA dikurangi.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

4. Efek samping

Seperti semua obat lainnya, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.

Perhatikan efek samping yang serius
Kesulitan bernapas - pernapasan lambat atau dangkal (depresi pernapasan) tidak umum terjadi pada orang yang menggunakan JURNISTA (dapat mempengaruhi hingga 1 dari 100 orang). Ini lebih mungkin mempengaruhi kelompok orang tertentu, seperti orang tua atau yang sangat lemah. Jika napas Anda menjadi sangat lambat atau dangkal, dan Anda merasa sangat mengantuk:
- terus bergerak dan berbicara sebanyak mungkin
- hubungi dokter Anda atau segera dapatkan bantuan medis darurat.

Bicarakan dengan dokter Anda tentang obat-obatan yang dapat digunakan untuk mengobati depresi pernapasan.

Reaksi alergi - ini jarang terjadi pada orang yang menggunakan JURNISTA (dapat mempengaruhi hingga 1 dari 100 orang). Tanda-tandanya meliputi:
- Pembengkakan wajah, bibir, mulut, lidah atau tenggorokan, yang dapat menyebabkan kesulitan menelan atau bernapas
- gatal gatal.

Hubungi dokter Anda atau dapatkan bantuan medis darurat segera jika Anda merasakan tanda-tanda ini. Dokter Anda dapat memutuskan jika JURNISTA tidak cocok untuk Anda.

Efek samping lainnya
Efek samping yang sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang)
- konstipasi; mual; muntah
- merasa mengantuk, lemah atau pusing; sakit kepala.

Efek samping yang umum (dapat mempengaruhi hingga 1 dari 10 orang)
- sesak napas
- diare; sakit perut; radang lambung dan usus
- gangguan pencernaan; memburuknya regurgitasi (aliran balik) makanan ke kerongkongan (sensasi seperti terbakar pada ulu hati); mulut kering
- dehidrasi; nafsu makan menurun; penurunan berat badan
- melihat atau mendengar hal-hal yang tidak ada (halusinasi)
- merasa bingung, cemas, gelisah atau gelisah
- depresi baru atau memburuk; perubahan mood
- merasa mengantuk; kesulitan tidur (insomnia); mimpi abnormal
- mudah lupa
- tremor atau kejang otot; kesemutan atau mati rasa pada kulit; penurunan rasa sentuhan atau sensasi, terutama di kulit
- penglihatan kabur; sensasi berputar (vertigo)
- tekanan darah tinggi
- peningkatan keringat; gatal; ruam kulit atau kemerahan
- nyeri, seperti nyeri sendi, otot, punggung atau ekstremitas
- nyeri saat buang air kecil
- kecanduan setelah obat dihentikan
- bengkak karena retensi cairan
- demam atau menggigil; perasaan tidak nyaman di dada
- jatuh; memar.

Efek samping yang tidak umum (dapat mempengaruhi hingga 1 dalam 100 orang)
- kesulitan bernapas (mengi), yang terjadi karena penyempitan saluran udara di paru-paru
- hidung berair
- peradangan atau penyumbatan usus; kantong di dinding bagian dalam usus besar; hemoroid
- perubahan gerakan usus, seperti bergantian antara konstipasi dan diare; tinja abnormal, seperti darah di tinja; kembung; masuk angin; bersendawa
- kesulitan menelan
- retensi cairan
- nafsu makan meningkat
- serangan panik; merasa paranoid, lesu, gelisah atau tegang; menangis
- perasaan bahagia yang berlebihan/ekstrim (euforia)
- dorongan seksual rendah
- gangguan tidur
- gangguan otak (encephalopathy)
- penurunan kewaspadaan atau kesadaran; kesulitan berkonsentrasi; kesulitan membentuk kata-kata atau berbicara
- merasa pingsan atau pingsan; kurang koordinasi; masalah keseimbangan
- gerakan berkedut, menyentak atau menggeliat tak terkendali; otot yang tiba-tiba menyentak; peningkatan indera peraba atau sensasi, terutama di kulit
- perubahan sensasi rasa
- penglihatan ganda; mata kering
- telinga berdengung (tinnitus)

- perubahan denyut jantung, seperti denyut jantung yang terlewati, cepat atau tidak teratur (palpitasi)
- tekanan darah rendah
- kemerahan pada kulit
- masalah buang air kecil, seperti ketidakmampuan untuk buang air kecil, kesulitan buang air kecil atau peningkatan frekuensi buang air kecil
- masalah dalam berhubungan seks atau impotensi
- gejala seperti flu, seperti merasa panas atau dingin
- masalah berjalan
- merasa gelisah, tidak normal atau umumnya tidak sehat
- overdosis obat
- penurunan kadar oksigen dalam darah; penurunan kadar kalium dalam darah; peningkatan tingkat enzim hati dalam darah.

Efek samping yang jarang (dapat mempengaruhi hingga 1 dalam 1.000 orang)
- pernapasan cepat atau dalam (hiperventilasi); bersin
- perforasi usus; hilangnya kontraksi di dinding usus; peradangan duodenum; lendir di anus
- gangguan dalam pengosongan perut; retensi cangkang tablet di lambung sehingga gagal melewati usus; buang air besar yang menyakitkan
- agresi
- sawan atau kejang
- gelisah atau hiperaktif; refleks berlebihan atau meningkat
- kesulitan dalam berpikir, mengingat informasi, atau memecahkan masalah
- pupil mengecil
- detak jantung lambat
- sensasi terbakar pada kulit
- merasa mabuk atau merasa seperti setelah mabuk
- penurunan suhu tubuh
- peningkatan kadar enzim 'amilase' dalam darah
- peningkatan kadar asam urat dalam darah, yang dapat menyebabkan encok
- penurunan kadar hormon seks, seperti penurunan kadar testosteron dalam darah.

Efek samping yang sangat jarang (dapat mempengaruhi hingga 1 dalam 10.000 orang)
- berhenti bernapas pada waktu tertentu pada saat tidur

Jika Anda mendapatkan efek samping tersebut, bicarakan dengan dokter atau apoteker Anda, termasuk semua efek samping yang tidak tercantum dalam informasi ini.

5. Bagaimana cara menyimpan JURNISTA

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Simpan obat ini dengan aman, di mana orang lain tidak dapat mengaksesnya. Obat ini mungkin dapat membahayakan orang-orang yang menggunakannya secara tidak sengaja, atau dengan sengaja ketika obat ini tidak diresepkan untuk mereka.

Jangan menggunakan JURNISTA setelah tanggal kedaluwarsa pada kemasan.

Jika Anda memiliki sisa tablet JURNISTA, jangan membuangnya ke dalam air limbah atau sampah rumah tangga. Tanyakan kepada apoteker Anda bagaimana cara membuang obat-obatan yang tidak lagi diperlukan. Hal ini membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Apakah kandungan dari JURNISTA

Zat aktif dari obat ini adalah hidromorfon hidroklorida. Tablet JURNISTA memiliki beberapa kekuatan yang berbeda.

Setiap 8 mg tablet mengandung 8,72 mg dan melepaskan 8 mg hydromorphone hidroklorida, setara dengan 7,12 mg hidromorfon.
Setiap 16 mg tablet mengandung 16,35 mg dan melepaskan 16 mg hydromorphone hidroklorida, setara dengan 14,24 mg hidromorfon.

Bahan-bahan lainnya adalah:
Butyl hydroxytoluene E321, asetat selulosa, gliserol triasetat, besi oksida hitam E172, hypromellose, laktosa, makrogol, magnesium stearat, polietilena oksida, povidone, propilen glikol, natrium klorida, titanium dioksida E171

Tablet 8 mg juga mengandung besi oksida merah E172.
Tablet 16 mg dan 32 mg juga mengandung besi oksida kuning E172.

Seperti apa JURNISTA dan isi kemasannya
Tablet 8 mg berwarna merah, bulat dan dicetak dengan 'HM 8' dengan tinta hitam di satu sisi.
Tablet 16 mg berwarna kuning, bulat dan dicetak dengan 'HM 16' dengan tinta hitam di satu sisi.

JURNISTA tersedia dalam kemasan blister berisi 7 tablet.

No. Reg: DNI1310900714BI (Jurnista 8mg)
No. Reg: DNI1310900714CI (Jurnista 16mg)

HARUS DENGAN RESEP DOKTER

Diproduksi oleh
ALZA corporation, Vacaville, USA

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Untuk pelaporan efek samping dan keluhan kualitas produk, dapat menghubungi drugsafety@jacid.jnj.com atau telp. (021) 2935-3935

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