

JURNISTA®

Hydromorphone hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about JURNISTA prolonged-release tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking JURNISTA against the benefits this medicine is expected to have for you.

If you have any concerns about taking JURNISTA, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What JURNISTA is taken for

JURNISTA is taken to relieve moderate to severe pain, which requires strong painkillers.

JURNISTA is only for patients with chronic, around the clock pain that is moderate to severe and expected to be long lasting. JURNISTA should not usually be the first medicine prescribed for your pain.

JURNISTA prolonged-release tablets contain a medicine called hydromorphone hydrochloride. This strong pain reliever belongs to a group of medicines known as opioid analgesics. Hydromorphone hydrochloride relieves pain by blocking the nerves that recognise pain messages from the body.

Your doctor may have prescribed JURNISTA for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you take JURNISTA

When you must not take it

Do not take JURNISTA if you:

- have an allergy to hydromorphone hydrochloride or any of the ingredients. See Product description at the end of this leaflet for a list of ingredients
- have been diagnosed with serious narrowing of the stomach and/or intestine (bowel)
- have pain resulting from very recent surgery or sudden pain which is long lasting
- have had surgery which may have left you with 'blind loop' in your intestine
- have seriously impaired liver function
- have serious breathing difficulties
- have severe acute asthma
- get sudden severe abdominal pain and the cause hasn't been diagnosed
- are taking a type of antidepressants called Monoamine Oxidase (MAO) inhibitors, or have taken them within the last 14 days
- are taking other morphine-related painkillers (buprenorphine, nalbuphine or pentazocine).

Do not take JURNISTA if the packaging is torn or shows signs of tampering.

Do not take JURNISTA beyond the expiry date (month and year) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not give JURNISTA to babies or children, women during pregnancy, labour, delivery, breastfeeding or patients who are in a coma.

Before you start to take it

You must tell your doctor if you:

- are pregnant or planning to become pregnant
- are breastfeeding or wish to breastfeed
- have or have ever had liver or kidney disease
- have or have ever had lung disease or difficulty in breathing
- have or have ever had heart disorders
- have or ever had headaches or head injuries
- have or ever had chronic constipation or any disease of your intestine including obstruction or inflammatory bowel disease
- have or ever had inflammation of the pancreas (pancreatitis) or disease of the bile duct
- have addiction to alcohol or drugs, or if you've had a severe reaction, such as confusion and shaking, to stopping alcohol (sometimes called delirium tremens)

- have or ever had symptoms of CNS depression such as severe drowsiness, low body temperature and sometimes coma
- have or ever had fits or seizures
- have an under-active thyroid (hypothyroidism) or problems with your adrenal gland
- have an enlarged prostate
- have difficulty in passing urine
- have a major mental disorder following an infection (toxic psychosis)
- have abnormal curvature of the spine (kyphoscoliosis)
- are planning to have a surgery
- are sensitive to sulfite.

You must tell your doctor if you have not used any opioid analgesics in the past, unless you are being treated for cancer pain. This is because you may be more likely to experience some of the side effects.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given JURNISTA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- other morphine-related painkillers (buprenorphine, nalbuphine or pentazocine).
- medicines used as antidepressants. In particular, antidepressants belonging to a group called monoamine oxidase inhibitors (MAOIs) should be stopped for 14 days before JURNISTA is taken. These include moclobemide, phenelzine sulfate and tranylcypromine sulfate.
- medicines used as sedatives, sleeping tablets, tranquillisers or muscle relaxants.

JURNISTA can increase the effect of drugs that are sedating or slow down your ability to react. A change in dose may be required if JURNISTA is taken with these medicines.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Effect on driving and operating machinery

JURNISTA can make you drowsy. Do not drive, operate machinery or do hazardous work until you are sure you are not affected. Take special care if your dose or type of medication is changed.

Effect of alcohol

Avoid alcohol when taking JURNISTA since their combined effect may cause drowsiness.

Warning: If your doctor has told you that you have intolerance to some sugars, including lactose, contact your doctor before taking JURNISTA.

Tolerance and Dependence

JURNISTA contains an opioid analgesic called hydromorphone hydrochloride. As with all opioid analgesics, over time your body becomes used to taking hydromorphone. Your doctor may, therefore, prescribe a higher dose of JURNISTA after some time to continue to give you pain relief. Also, if you suddenly stop taking JURNISTA you may experience some symptoms of withdrawal.

Taking JURNISTA

How to take the tablet

Adults

JURNISTA is available in five different strengths. Your doctor will decide which strength is suitable to control your pain.

The usual starting dose of JURNISTA is 8 mg taken at the same time each day. However, your doctor may prescribe a different dose of JURNISTA to

start with if you are changing from a different morphine-related painkiller.

JURNISTA should be swallowed whole, with a glass of water.

JURNISTA may be taken with or without food.

DO NOT crush or chew the tablets. If you do, there is a danger you could overdose, because the medicine will be released into your body too quickly.

Do not take JURNISTA more than once every 24 hours. If you have insufficient pain relief from JURNISTA you should contact your doctor for advice. Taking another JURNISTA tablet some time after a first tablet on the same day could result in too much medicine being released into your body.

Ask your doctor or pharmacist for help if you do not understand the instructions provided with this medicine.

Children

JURNISTA should not be given to children and adolescents under 18 years of age.

If you forget to take it

If you forget to take a tablet, take the next dose immediately and start a new 24-hour regimen. If you are not sure what to do, check with your doctor or pharmacist. **DO NOT** take extra tablets or double dose to make up for the forgotten tablets.

If you have trouble remembering when to take the tablet, ask your pharmacist for some hints.

If you take too much (overdose)

The most important sign of overdose is difficulty in breathing. Other signs of overdose are feeling very drowsy, an increased heart rate, clammy skin, small pupils, low blood pressure and coma. Someone who's taken a serious overdose may stop breathing, have a heart attack and die.

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to the Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

Australia: 13 11 26
New Zealand: 0800 764 766 or 0800 POISON

Keep these telephone numbers handy.

INFORMATION FOR THE DOCTOR

In case of overdose: administer an opioid antagonist and transfer patient to hospital.

Please refer to full Product Information for details on appropriate management of overdose.

While you are taking JURNISTA

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while taking JURNISTA.
- If your pain continues or returns, see your doctor. You may need additional medicines to control the pain or a change in the strength of the JURNISTA tablet.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking JURNISTA.

DO NOT be alarmed if you notice what appears to be the JURNISTA tablet in your stool; this is simply the non-dissolvable shell of the tablet.

Things you must not do

- **DO NOT use JURNISTA to treat any other complaint unless your doctor says so.**
- **DO NOT give the tablets to anyone else, even if their symptoms seem similar to yours.**
- **DO NOT stop taking JURNISTA unless your doctor advises you to do so.**

If you have been taking JURNISTA for a long period of time but stop taking it suddenly without your doctor's advice, you may experience withdrawal symptoms such as:

- anxiety or irritability
- vomiting or feeling sick
- diarrhoea or stomach pain
- the pupils of your eyes increasing in size
- blushing or sweating
- crying for no reason
- pains in your joints.

Seek your doctor's advice if you experience any of these symptoms.

Do not crush and intravenously inject JURNISTA. Animal studies have shown that some of the non-active components of JURNISTA can cause serious damage to organs such as the heart, kidneys, and blood cells and even death, when injected intravenously. When taken by mouth as instructed by your doctor these non-active components of JURNISTA are not absorbed into the body and are well tolerated.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following:

- nausea, vomiting, cramps, diarrhoea, fever, stomach pain or discomfort, constipation, dry mouth, indigestion, difficulty in swallowing, excessive gas in the stomach or bowel, passage of stools containing blood, piles, abnormal faeces, belching, torn rectum, inflammation of the small intestine, bowel obstruction, painful defecation
- loss of appetite, weight decrease, dehydration, fluid retention, increased appetite, high uric acid levels in the blood, which may cause gout
- nervousness, confusion, hallucinations, euphoria, depression, trouble sleeping, anxiety, abnormal dreams, restlessness, altered mood, decreased sexual drive, panic attack, listless, paranoia, aggression, crying, erectile dysfunction
- trouble in urinating, pain when passing urine, urinary hesitation, frequent day time urination
- sleepiness, headache, dizziness, increased or decreased feeling, pins and needles, shaking, memory impairment, disturbance in attention, taste disorder, speech disorder, balance disorder, abnormal coordination, uncontrollable twitching, cognitive disorder, convulsion, unusually increased reflexes, buzzing or whistling in the ears
- blurred vision, double vision, dry eyes, contraction of the pupil
- itching, excessive sweating, rash, redness of the skin, skin burning sensation, sneezing
- muscle spasms, back pain, joint pain, pain in extremity, aching muscles
- weakness, pain, chills, drug withdrawal symptoms, feeling unwell or abnormal, difficulty in walking, influenza-like illness.

Tell your doctor immediately if you experience any of the

following, as you may need urgent medical care:

- fainting, decreased level of consciousness, cognitive disorder
- fast or irregular heart rate, extra heart beats
- flushing, high or low blood pressure
- shortness or difficulty in breathing, lack of oxygen, respiratory depression, fast breathing
- swelling of the face, lips, mouth, tongue or throat, fever or high temperature, chest discomfort.

After taking JURNISTA

Storage

Keep JURNISTA tablets in the blister pack and box until it is time to take them.

Keep the tablets in a cool dry place where temperature is below 25°C.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store JURNISTA tablets or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking JURNISTA, or the tablets have passed their expiry date, return the tablets to your pharmacist.

Product description

What it looks like

- JURNISTA 4 mg prolonged-release tablets are pale beige and

have "HM 4" printed in black ink on one side

- JURNISTA 8 mg prolonged-release tablets are red and have "HM 8" printed in black ink on one side
- JURNISTA 16 mg prolonged-release tablets are yellow and have "HM 16" printed in black ink on one side
- JURNISTA 32 mg prolonged-release tablets are white and have "HM 32" printed in black ink on one side
- JURNISTA 64 mg prolonged-release tablets are blue and have "HM 64" printed in black ink on one side.

JURNISTA is provided in blister packs of 14 tablets. Blister packs of 7, 10, 20, 28, 30, 35, 40, 50, 60 and 100 tablets are currently not marketed.

JURNISTA 4 mg (AUST R 155995)

JURNISTA 8 mg (AUST R 141508)

JURNISTA 16 mg (AUST R 141533)

JURNISTA 32 mg (AUST R 141534)

JURNISTA 64 mg (AUST R 141535)

Ingredients

Each JURNISTA tablet contains 4 mg, 8 mg, 16 mg, 32 mg or 64 mg of hydromorphone hydrochloride as the active ingredient.

Each tablet also contains the following other ingredients:

- **Coated tablet core:** polyethylene oxide, povidone, magnesium stearate, butylhydroxytoluene (E321), sodium chloride, hypromellose, iron oxide black (E172), lactose anhydrous, cellulose acetate, macrogol 3350 and iron oxide yellow (E172) (32 mg tablet only).
- **Colour overcoat:** lactose monohydrate, hypromellose, titanium dioxide

(E171), glycerol triacetate, iron oxide red (E172) (4 mg & 8 mg tablet)/iron oxide black (4 mg tablet)/iron oxide yellow (E172) (4 mg & 16 mg tablet)/indigo carmine lake (E132) (64 mg tablet).

- **Clear overcoat:** hypromellose and macrogol 400.
- **Printing ink:** iron oxide black (E172), propylene glycol and hypromellose.

Sponsor

Janssen-Cilag Pty Ltd
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NZ Office: Auckland New Zealand
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