

PACKAGE LEAFLET: INFORMATION FOR THE USER

<Tradename> 1.3 mg capsules, hard

<Tradename> 2.6 mg capsules, hard

Hydromorphone hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4..

What is in this leaflet:

1. What **<Tradename>** is and what it is used for
2. What you need to know before you take **<Tradename>**
3. How to take **<Tradename>**
4. Possible side effects
5. How to store **<Tradename>**
6. Contents of the pack and other information

1. WHAT **<Tradename> IS AND WHAT IT IS USED FOR**

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE **<Tradename>**

Do not take **<Tradename> if you:**

- are allergic (hypersensitive) to hydromorphone or any of the other ingredients of the capsules (see section 6 'Further Information');
- have breathing problems, such as severe chronic obstructive airways disease or respiratory depression. Symptoms may include breathlessness, coughing or breathing more slowly and weakly than expected;
- have a sudden severe pain in your abdomen (acute abdomen);
- have a condition where the bowel does not work properly (paralytic ileus);
- are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks.

Warnings and precautions

Before treatment with these capsules tell your doctor or pharmacist if you:

- have a severe headache or feel sick due to a head injury or increased pressure in your skull (for instance due to brain disease). This is because the capsules may make symptoms worse or hide the extent of a head injury;
- suffer from seizures, fits or convulsions;
- have a mental disorder as a result of an intoxication (toxic psychosis);
- have low blood pressure (hypotension);
- are feeling light headed or faint;
- have gall bladder or bile duct problems;
- have colicky abdominal pain or discomfort;
- have inflammation of the pancreas (which may cause severe pain in the abdomen and back);
- have a blockage of the gut or inflammatory bowel disorder;
- have an enlarged prostate gland, which causes difficulty in passing urine (in men);

- have poor adrenal gland function e.g. Addison's disease (your adrenal gland is not working properly);
- have an under-active thyroid gland (hypothyroidism);
- have breathing problems, such as chronic obstructive airways disease or reduced respiratory reserve. Symptoms may include breathlessness and coughing;
- have severe kidney or liver problems;
- are or have ever been addicted to alcohol or drugs;
- have withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol or drugs;

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

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

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

The capsule contents should never be injected as this may lead to serious side effects, which may be fatal.

Other medicines and <Tradename>

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you take these capsules with some other medicines, the effect of the capsules or the other medicine may be changed.

These capsules must not be used together with a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks (see section 2 'Do not take...').

Tell your doctor or pharmacist if you are taking:

- medicines to help you sleep or stay calm (for example tranquillisers, hypnotics or sedatives including benzodiazepines);
- medicines known as barbiturates to either treat fits or to help you sleep;
- medicines to stop you feeling or being sick;
- medicines to prevent or relieve the symptoms of an allergy (antihistamines);
- medicines to treat depression;
- medicines to treat psychiatric or mental disorders (antipsychotics such as phenothiazines);
- other strong analgesics ('painkillers').

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

Concomitant use of <Tradename> and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe <Tradename> together with sedative medicines the dose and duration of treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Taking <Tradename> with food, drink and alcohol

These capsules can be taken with or without food but should not be taken with alcohol.

Drinking alcohol during your treatment with these capsules may make you sleepy or adversely affect your breathing.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should not use these capsules during pregnancy and labour unless you have been specifically told by your doctor. Depending on the dose and duration of therapy with hydromorphone slow and shallow breathing (respiratory depression) or withdrawal symptoms may occur in the newborn infant. Newborn babies may suffer withdrawal effects (such as high-pitched cry, jitteriness, fits, poor feeding and diarrhoea) if their mothers have taken hydromorphone for a long time during pregnancy.

Breast-feeding

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

Driving and using machines

These capsules may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the capsules, or when changing to a higher dose. If you are affected you should not drive or use machinery.

<Tradename> contains lactose

These capsules contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these capsules.

3. HOW TO TAKE <Tradename>

Always take the capsules exactly as your doctor has told you. The label on your medicine will tell you how many capsules to take and how often.

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

Swallow your capsules whole with a glass of water. If you prefer, you can open the capsules and sprinkle the contents on to cold soft foods, such as yoghurt. You must only take the capsules by mouth.

Adults and children over 12 years of age

The usual starting dose is one capsule every 4 hours. However, your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these capsules discuss this with your doctor.

Children under 12 years of age

Children under 12 years of age should not take the capsules.

Elderly patients and patients with kidney or liver problems

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

If you take more <Tradename> than you should or if someone accidentally swallows your capsules

Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy, sick or dizzy and may also develop pinpoint pupils, breathing problems, low blood pressure, or pneumonia caused by inhaling vomit or foreign matter (symptoms may include breathlessness, cough and fever). In severe cases an overdose may lead to unconsciousness or even death. When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show the doctor.

If you have taken too many capsules under no circumstances should you put yourself in a situation that requires you to be alert e.g. driving a car.

If you forget to take <Tradename>

If you miss a dose you should take it as soon as you remember and then carry on as before. Do not take two doses within 4 hours. Do not take a double dose to make up for a forgotten capsule.

If you stop taking <Tradename>

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, these capsules can cause side effects, although not everybody gets them.

This medicine can cause allergic reactions (hypersensitivity reactions) which may be serious (anaphylactic reactions). The frequency of these reactions is not known. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face, lips, mouth or throat, or any rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression – a typical hazard of an opioid overdose).

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

Very common (may affect more than 1 in 10 people taking these capsules)

- Constipation (your doctor can prescribe a laxative to overcome this problem).
- Feeling sick.
- Dizziness, feeling more sleepy than normal.

Common (may affect up to 1 in 10 people taking these capsules)

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

Uncommon (may affect up to 1 in 100 people taking these capsules)

- Withdrawal symptoms (see section 3 'If you stop taking <Tradename>').
- Indigestion, diarrhoea, changes in taste.
- Depression, a feeling of extreme happiness, hallucinations, nightmares.
- Blurred vision.
- Agitation.
- Tremor, muscle spasms, tingling or numbness.

- Low blood pressure.
- A shortness of breath.
- Decreased sexual drive, impotence.
- Rash.
- Swelling of the feet, ankles or hands.
- Difficulty in passing urine.
- Generally feeling unwell.
- Tiredness.
- A worsening in liver function tests (seen in a blood test).

Rare (may affect up to 1 in 1,000 people taking these capsules)

- Aggression.
- Feeling far more sleepy than normal.
- Lack of energy.
- A fast heart beat, a slow heart beat, palpitations.
- Wheezing or difficulty in breathing.
- A worsening in pancreas function tests (seen in a blood test).

Not known (frequency cannot be estimated from the available data)

- Seizures, fits or convulsions.
- An unpleasant or uncomfortable mood.
- An increase in sensitivity to pain.
- A condition where the bowel does not work properly (paralytic ileus).
- A reduction in size of the pupils in the eye.
- Flushing
- Uncontrolled muscle movements.
- Hives.
- A need to take increasingly higher doses to gain the same level of pain relief (tolerance).
- Withdrawal symptoms in babies born to mothers who have used hydromorphone (see section 2).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE *<Tradename>*

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

Do not use these capsules after the expiry date which is stated on the blister and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What *<Tradename>* contains

The active ingredient is hydromorphone hydrochloride. Each capsule contains 1.3 mg of hydromorphone hydrochloride equivalent to 1.16 mg hydromorphone or 2.6 mg of hydromorphone hydrochloride equivalent to 2.32 mg of hydromorphone.

The other ingredients are:

- Microcrystalline cellulose
- Lactose anhydrous
- Gelatin
- Sodium laurilsulfate
- Shellac
- Erythrosine (E127)
- Titanium dioxide (E171)
- Iron oxide (E172)
- Propylene glycol

What <Tradename> look like and the contents of the pack

<Tradename> 1.3 mg are capsules which have a hard gelatin shell containing white to off-white spherical pellets with clear uncoloured caps and opaque orange bodies. The capsules are marked with “HNR 1.3”.

<Tradename> 2.6 mg are capsules which have a hard gelatin shell containing white to off-white spherical pellets with opaque red caps and clear uncoloured bodies. The capsules are marked with “HNR 2.6”.

The capsules are packed in blisters then placed in boxes. In each box there are 20, 28, 30, 50, 56, 60, 98 or 100 * capsules.

(*The printed leaflet will refer to marketed pack sizes only)

Marketing Authorisation Holder and Manufacturer

< To be completed nationally >

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany	Hydromorphon Krugmann 1,3 mg Hartkapseln
	Hydromorphon Krugmann 2,6 mg Hartkapseln
Republic of Ireland	Hydromorphone-HCl Krugmann 1.3 mg capsules, hard
	Hydromorphone-HCl Krugmann 2.6 mg capsules, hard

This leaflet was last revised in {MM/YYYY}

Trademark registration details: <To be completed Nationally >

ADDITIONAL MEMBER STATE SPECIFIC INFORMATION TO BE AGREED ON A NATIONAL BASIS

Germany

Section 2:

Effects of abuse as a performance-enhancing drug

The use of <Tradename> may produce positive results in doping controls.

Section 4

Evaluation of side effects is based on the following frequency information:

Very common:	affects more than 1 patient in 10
Common:	affects 1 to 10 patients in 100
Uncommon:	affects 1 to 10 patients in 1,000
Rare:	affect 1 to 10 patients in 10,000
Very rare:	affects less than 1 patient in 10,000
Not known:	frequency cannot be estimated from the available data