Package leaflet: Information for the patient

< Hydofon 2 mg/ml - Solution for injection/infusion>
< Hydofon 10 mg/ml - Solution for injection/infusion>
< Hydofon 20 mg/ml - Solution for injection/infusion>
< Hydofon 50 mg/ml - Solution for injection/infusion>
Hydromorphone hydrochloride

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Product name> is and what it is used for

<Product name> contains the active substance hydromorphone hydrochloride, which is a potent analgesic ("painkiller") of the opioid group.

You have been prescribed <Product name> for the treatment of severe pain.
This medicine is intended for use in adults and adolescents over 12 years of age.

2. What you need to know before you are given <Product name>

You must not be given <Product name> if:
- you are allergic to hydromorphone or to any of the other ingredients of this medicine (listed in section 6);
- you have breathing problems (respiratory depression);
- you suffer from a severe lung disease associated with obstruction of the airways (severe chronic obstructive pulmonary disease or severe COPD);
- you suffer from bronchial asthma
- you have heart problem after long-term lung disease (cor pulmonale);
- you have severe pain in your abdomen;
- you have a condition where the small bowel does not work properly (paralytic ileus);
- you are taking a type of medicine known as monoamine oxidase inhibitor (examples include tranylcypromide, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks.

<Product name> must not be used if the patient is in a coma.

Warnings and precautions

Talk to your doctor before you are given <Product name> if:
- your breathing is severely impaired;
- you have breathing problems during sleep (sleep apnoea);
- you receive concomitant treatment with CNS depressants (such as sedatives, hypnotics or tranquilizers; see section "Other medicines and <Product name>");
- you have a head injury (due to the risk of increased brain pressure), or if your consciousness is decreased without any known reason;
- you suffer from seizures, fits or convulsions;
- you suffer from a mental disorder as a result of an intoxication (toxic psychosis);
- you have previously suffered from withdrawal symptoms such as agitation, anxiety, nervousness, difficulty in sleeping, being unusually overactive, shaking and gastrointestinal problems upon stopping taking alcohol or drugs;
- you have low blood pressure associated with low circulating blood volume (hypotension with hypovolaemia);
- you are feeling light-headed or faint;
- you have problems with your gall bladder;
- you have inflammation of the pancreas (pancreatitis);
- you have any bowel problems (such as obstructive or inflammatory bowel disease or constipation);
- you have prostate problems (such as difficulties in passing urine);
- you have poor adrenal gland function (e.g. Addison's disease).
- you have an under-active thyroid gland (hypothyroidism);
- you have a chronic obstructive airway disease (such as COPD) or reduced pulmonary function;
- you suffer from a debilitated general condition or are elderly or infirm;
- you suffer from severe kidney problems (including ureteric colic);
- you suffer from severe liver problems.

Tolerance, dependence and addiction

This medicine contains hydromorphone, which is an opioid. It can cause dependence and/or addiction.

This medicine contains hydromorphone which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of <Product name> can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to use or how often you need to use it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on <Product name> if:
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ('addiction').
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst using <Product name>, it could be a sign that you have become dependent or addicted:
- You need to use the medicine for longer than advised by your doctor.
- You need to use more than the recommended dose.

- You might feel that you need to carry on using your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'.
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine.
- When you stop using the medicine you feel unwell, and you feel better once using the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (see section 3, If you stop using <Product name>).

Sleep-related breathing disorders
<Product name> can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

An increase in sensitivity to pain (hyperalgesia) that will not respond to a further dose increase of <Product name> may very rarely occur in particular in high doses. Your doctor will decide whether a dose reduction or change in analgesic (opioid) is required in such a situation.

Similar to other opioids, <Product name> may affect the normal production of hormones in the body such as cortisol or sex hormones, particularly if you have used high doses for long periods of time.

If this information applies to you or formerly applied to you, please speak to your doctor.

Please tell your doctor, if you experience small bowel problems (paralytic ileus) during the treatment with <Product name>. He will take appropriate measures.

If you are going to have a surgery, please tell your doctor at the hospital that you are using <Product name> as they may need to adjust the amount of injection you are given.

<Product name> 2 mg/ml [10 mg/ml, 20 mg/ml, 50 mg/ml] solution for injection or infusion is not recommended for children under 12 years of age.

Other medicines and <Product name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

When used with some other medicines or alcohol, the side effects of <Product name> (such as drowsiness, breathing problems, constipation, dry mouth, difficulty in passing urine) or the other medicine may be altered.

Tell your doctor:
- if you are taking medicines to treat anxiety (for example tranquillisers);
- if you have been given an anaesthetic (for example a barbiturate);
- if you are taking medicines to help you sleep (hypnotics or sedatives);
- if you are taking medicines to treat psychiatric or mental disorders (neuroleptics or psychotropics);
- if you are taking medicines to treat depression (antidepressants);
- if you are taking medicines used to stop you feeling sick or being sick (antiemetics);
- if you are taking medicines used to prevent or relieve the symptoms of an allergy (antihistamines);
- if you are taking medicines to treat Parkinson's disease;
- if you are taking other strong analgesics or 'painkillers', or have recently taken another painkiller from the opioid class.

You must not be given <Product name> if you are taking a specific type of medicine known as monoamine oxidase inhibitor, or you have taken this type of medicine in the last two weeks.

Concomitant use of <Product name> and sedative medicines such as benzodiazepines (that can help to reduce anxiety and seizures, relax the muscles, and induce sleep) 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. The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening.

However, if your doctor does prescribe <Product name> together with sedative medicines the dose and duration of concomitant 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.

<Product name> with alcohol
Drinking alcohol during your treatment with <Product name> may make you drowsy. If you are affected you should avoid drinking alcohol.

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 you are given this medicine.

Pregnancy
You should not use <Product name> during pregnancy and labour unless you have been specifically told by your doctor. If you use <Product name> during labour uterine contractility may be impaired. In addition slow and shallow breathing (respiratory depression) 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
<Product name> should not be used while breast-feeding because the medicine can get into breast milk.

Driving and using machines
<Product name> may make you drowsy and thus impair your ability to drive and use machines. This applies particularly:
- at the beginning of treatment;
- if your dose is increased;
- if you have switched to <Product name> from a different opioid.
- if you drink alcohol or use medicines which influence your brain function.

You should consult your doctor before driving or using machinery.

<Product name> contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially "sodium-free".

3. How <Product name> is given

A doctor or nurse will usually prepare and administer the injection for you.

Your doctor will decide how much <Product name> you require based on:
- the severity of your pain;
- the dose of painkiller you have previously been given;
- your age and weight.

Your doctor will increase the amount of <Product name> you are given until your pain is relieved. If you find that you are still in pain whilst undergoing treatment with <Product name>, discuss this with your doctor.

You should not use <Product name> 10 mg/ml [20 mg/ml, 50 mg/ml] as initial opioid therapy. This higher dosage form may only be used as individual doses if you have no longer sufficiently responded to lower doses of hydromorphone preparations or comparably strong analgesics as part of long term pain therapy.

The usual starting doses of <Product name> are as follows:

Use in adults and adolescents (older than 12 years of age)
- As a single injection into a vein, the usual dose is 1 to 1.5 mg given slowly over 2 to 3 minutes. This can be repeated every 3 to 4 hours.
- As a single injection through a fine needle into the tissue under the skin, the usual dose is 1 to 2 mg. This can be repeated every 3 to 4 hours.
- As an infusion into a vein or through a fine needle into the tissue under the skin, the usual starting dose is 0.15 to 0.45 mg/hour (or 0.004 mg/kg bodyweight/hour).
- If given by patient controlled analgesia (PCA), the usual recommended bolus dose is 0.2 mg with a stop interval of 5 to 10 minutes.

Use in children (under 12 years of age)
<Product name> 2 mg/ml [10 mg/ml, 20 mg/m, 50 mg/ml] solution for injection/infusion is not recommended for children under 12 years of age.

Use in elderly patients (over 75 years of age)
A lower dosage might be enough for adequate pain relief in elderly patients.

Use in patients with liver and kidney problems
If you suffer from liver or kidney problems, you may require less <Product name> in order to relieve your pain.

How you are given <Product name>A doctor or healthcare professional will usually administer <Product name> for you.

<Product name> is intended for injection or infusion into a vein (intravenous = i.v.) or through a fine needle under the skin (subcutaneous = s.c.).

Duration of treatment
<Product name> should only be used as long as necessary. Your doctor will decide when and how the treatment will be stopped. If you get a long term treatment, your doctor should verify regularly whether you still need <Product name>. Do not stop the treatment without talking to your doctor (see "If you stop using <Product name>").

If you use more <Product name> than you should
Call your doctor or hospital straight away. In severe cases an overdose may lead to unconsciousness or even death. The following symptoms may occur after an overdose:
- pin point pupils;
- slowing of heartbeat;
- respiratory problems;

- low blood pressure;
- unconsciousness leading to coma;
- pneumonia caused by inhaling vomit or foreign matter (with symptoms such as breathlessness, cough and fever).

If you have used too much <Product name> injection under no circumstances should you put yourself in a situation that requires you to be alert e.g. driving a car.
You may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining ampoules with you to show to the doctor.

If you forget to use <Product name>
Please use <Product name> as soon as you noticed that you forgot it. Never use a double dose to make up for a forgotten dose.

If you forgot to use <Product name> or used a smaller dose than prescribed, this will lead to unsatisfactory and/or insufficient pain relief.

If you stop using <Product name>
You should not suddenly stop using <Product name> unless your doctor tells you to. If you want to stop using <Product name>, discuss this with your doctor first.
If you do stop using <Product name> suddenly after longer treatment, you may experience withdrawal symptoms such as agitation, anxiety, nervousness, difficulty in sleeping, involuntary muscle contractions, shaking, and gastro-intestinal problems.
Your doctor will tell you how to stop treatment, usually by reducing the dose gradually so you do not experience unpleasant effects.

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

4. Possible side effects

Like all medicines , this medicine can cause side effects, although not everybody gets them.

This medicine can cause allergic reactions (hypersensitivity reactions). The incidence of serious allergic reactions (anaphylactic 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, rash or itching especially those covering your whole body.

Difficulty in breathing (respiratory depression) is the chief hazard of an opioid overdose.

Most people will have constipation when using <Product name>. Increasing the amount of fibre (fruit, vegetables, wholemeal bread, pasta, brown rice) and fluids you eat and drink may help reduce the problem, but if necessary your doctor may prescribe a laxative.

You may feel sick or vomit (be sick) when you use <Product name>. This should normally wear off after a few days, however your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.

Other possible side effects:

Very common (may affect more than 1 in 10 patients treated)
- dizziness, feeling more sleepy than normal
- constipation
- feeling sick

Common (may affect up to 1 in 10 patients treated)

- anxiety, confusion, sleeplessness
- dry mouth, being sick (vomiting)
- itchy skin, sweating
- urgency in passing urine
- a feeling of unusual weakness
- decreased appetite
- headache
- abdominal pain
- skin reactions at the injection site

Uncommon (may affect up to 1 in 100 patients treated)
- agitation, depression, nightmares
- feeling of extreme happiness (euphoria), hallucinations
- shaking, involuntary muscle contractions, tingling in the hands or feet
- visual impairment
- low blood pressure
- indigestion (dyspepsia)
- rash
- difficulty in passing urine
- decreased sexual drive, impotence
- withdrawal symptoms such as agitation, anxiety, nervousness, difficulty in sleeping, being unusually overactive, movements, shaking and gastrointestinal problems
- difficulty in breathing (dyspnoea)
- diarrhoea, taste changes
- may affect the results of blood tests to check that your liver is working properly
- tiredness, generally feeling unwell,
- swelling of hands, ankles or feet

Rare (may affect up to 1 in 1.000 patients treated)
- sedation
- slow, irregular or fast heartbeat
- difficulty in breathing or wheezing
- may affect the results of blood tests to check that your pancreas is working properly
- redness of the face (facial flushing)
- lack of energy

Very rare (may affect less than 1 of 10.000 patients treated)
- irritation and hardening of the skin at the injection site (particularly after repeated injections under the skin)

Not known (frequency cannot be estimated from the available data)
- drug dependence
- unpleasant or uncomfortable mood (dysphoria)
- seizures, fits or convulsions
- breathing problems during sleep (sleep apnoea syndrome)
- uncontrolled muscle movements
- drug tolerance
- an increase in sensitivity to pain (hyperalgesia; see “Warnings and precautions” in section 2)
- a condition where the small bowel (part of your gut) does not work properly (paralytic ileus)
- reduction in size of the pupils in the eye (miosis)
- hot flashes
- itching rash (urticaria)

- withdrawal symptoms of newborns, whose mothers have used <Product name> during pregnancy (see section 2 Pregnancy and breast-feeding)
- sleep apnoea (breathing pauses during sleep)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 <Product name>

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

Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Instructions for stability after use or dilution:
After opening, this medicinal product should be used immediately.

Chemical and physical in-use stability has been demonstrated for 7 days at 5°C, and for 48 hours at 25°C and 37°C except for diluted solutions in polycarbonate syringes which should not be stored for more than 24 hours..

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

The medicinal product is to be visually inspected prior to use and also after dilution. Only clear solutions free from visible particles should be used.

For single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What <Product name 2 mg/ml [10 mg/ml, 20 mg/ml, 50 mg/ml]> contains

<Product name> 2 mg/ml:
The active substance is hydromorphone hydrochloride. Each 1 ml ampoule contains 2 mg hydromorphone hydrochloride (corresponding to 1.77 mg hydromorphone).

<Product name> 10 mg/ml:
The active substance is hydromorphone hydrochloride.
Each 1 ml ampoule contains 10 mg hydromorphone hydrochloride (corresponding to 8.87 mg hydromorphone).
Each 10 ml ampoule contains 100 mg hydromorphone hydrochloride (corresponding to 88.7 mg hydromorphone).

<Product name> 20 mg/ml:
The active substance is hydromorphone hydrochloride.
Each 1 ml ampoule contains 20 mg hydromorphone hydrochloride (corresponding to 17.73 mg hydromorphone).

<Product name> 50 mg/ml:
The active substance is hydromorphone hydrochloride.
Each 1 ml ampoule contains 50 mg hydromorphone hydrochloride (corresponding to 44.33 mg hydromorphone).

The other ingredients are: sodium chloride, sodium citrate, citric acid monohydrate, water for injections.

What <Product name 2 mg/ml [10 mg/ml, 20 mg/ml, 50 mg/ml]> looks like and contents of the pack

<Product name> 2 mg/ml [20 mg/ml, 50mg/ml] is a clear, colourless to pale yellow solution for injection/infusion supplied in clear glass ampoules, available in packs of 5 x 1 ml ampoules.

<Product name> 10 mg/ml is a clear, colourless to pale yellow solution for injection/infusion supplied in clear glass ampoules, available in packs of 5 x 1 ml or 10 ml ampoules.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

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Detailed information on this medicine is available on the website of {name of MS Agency (link)}

The following information is intended for healthcare professionals only:

<Product name 2 mg/ml - Solution for injection/infusion>
<Product name 10 mg/ml - Solution for injection/infusion>
<Product name 20 mg/ml - Solution for injection/infusion>
<Product name 50 mg/ml - Solution for injection/infusion>
Hydromorphone hydrochloride

Posology and method of administration

Method of administration:
Intravenous injection or infusion.
Subcutaneous injection or infusion.
<Product name> is intended for single use only.
The medicinal product is to be visually inspected prior to use. Only clear solutions free from visible particles should be used.
After opening, this medicinal product should be used immediately.

Posology

The dosing of <Product name> has to be adjusted to the patients' severity of pain and to their individual response.
The dose should be titrated until optimum analgesic effect is achieved.
While a sufficiently high dose should generally be administered, the smallest dose to achieve analgesia should be aimed at in the individual case.

<Product name> 10 mg/ml [20 mg/ml mg and 50 mg/ml] is not suitable for initial opioid therapy. These higher dosage forms may only be used as individual doses in patients who have no longer sufficiently responded to lower doses of hydromorphone preparations (<Product name> 2 mg/ml) or comparably strong analgesics within the scope of chronic pain therapy. The reservoir of a pain pump can also be filled with individual doses of 10 mg, 20 mg or 50 mg as the dose control is secured by the pump calibration.

Treatment goals and discontinuation
Before initiating treatment with <Product name>, a treatment strategy including treatment duration and treatment goals, and a plan for end of the treatment, should be agreed together with the patient, in accordance with pain management guidelines. During treatment, there should be frequent contact between the physician and the patient to evaluate the need for continued treatment, consider discontinuation and to adjust dosages if needed. When a patient no longer requires therapy with hydromorphone, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. In absence of adequate pain control, the possibility of hyperalgesia, tolerance and progression of underlying disease should be considered.

Duration of treatment
Hydromorphone should not be used longer than necessary.

Age	Method of administration	Bolus	Infusion
Adults and adolescents (> 12 years)	subcutaneous (s.c.) use	1-2 mg s.c. every 3-4 hours	0.15-0.45 mg/h and 0.004 mg/kg bodyweight/h, resp.
	intravenous (i.v.) use	1-1.5 mg i.v. every 3-4 hours to be injected slowly over at least 2-3 minutes	0.15-0.45 mg/h and 0.004 mg/kg bodyweight/h, resp.
	PCA (s.c. and i.v.)	0.2 mg bolus, stop interval 5-10 min.	
Children (< 12 years)	Not recommended.		

<Product name> is not recommended for use in children under 12 years of age due to insufficient data on safety and efficacy.

Elderly patients
Elderly patients (as a rule over 75 years) may require a lower dosage than other adults to achieve adequate analgesia.

Patients with hepatic and/or renal impairment
These patients may require lower doses than other patient groups to achieve adequate analgesia. They should be carefully titrated to clinical effect.

Shelf life

Shelf life of unopened ampoules: 30 months
Shelf life after first opening: For immediate use.

Chemical and physical in-use stability has been demonstrated for 7 days at 5°C, and for 48 hours at 25°C and 37°C, except for diluted solutions in polycarbonate syringes, which should not be stored for more than 24 hours.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Special precautions for disposal and other handling

Incompatibilities were observed with diluted solutions of 50 mg/ml when stored in polycarbonate syringes beyond 24 hours at 25°C. Whereas no evidence of incompatibility was found when the same precautions preparations were stored at 4°C up to 7 days.
No evidence of incompatibility was observed between <Product name> undiluted and diluted with sodium chloride 9 mg/ml (0.9%) solution for infusion, glucose 50 mg/ml (5%) solution for infusion or water for injections, and representative brands of polypropylene syringes, polyethylene and PVC tubing and PVC or EVA infusion bags.
No evidence of incompatibility was observed between <Product name> undiluted and diluted with sodium chloride 9 mg/ml (0.9%) solution for infusion or water for injections and representative brands of injectable forms of the following medicinal products, when stored in high and low dose combinations in polypropylene syringes over a 24 hour period at ambient temperature (25°C):
Hyoscine butylbromide
Hyoscine hydrobromide
Dexamethasone sodium phosphate
Haloperidol
Midazolam hydrochloride
Metoclopramide hydrochloride
Levomepromazine hydrochloride
Glycopyrronium bromide
Ketamine hydrochloride

This medicinal product must not be mixed with other medicinal products except those mentioned above.
Inappropriate handling of the undiluted solution after opening of the original ampoule, or of the diluted solutions may compromise the sterility of the product.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.