PACKAGE LEAFLET: INFORMATION FOR THE USER

Diamorphine Hydrochloride 5mg, 10mg, 30mg, 100mg and 500mg for Injection

Travel Direction

This medicine contains diamorphine hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.
Read all of this leaflet carefully before you start using 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, nurse or pharmacist.
- 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 Diamorphine Injection is and what it is used for

This medicine had been prescribed for you to relieve moderate to severe pain. Diamorphine is used for the relief of severe pain associated with surgical procedures, heart attack and pain in terminally ill patients. It is also used to treat breathlessness caused by fluid in the lungs.
It contains diamorphine hydrochloride which belongs to a class of medicines called opioids, which are 'pain relievers'.
This medicine has been prescribed to you and should not be given to anyone else.
Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you are given Diamorphine Injection

Diamorphine Injection should not be given if you:
- have ever had a reaction to or been told that you are allergic to diamorphine or morphine
- have been told you have a tumour of the adrenal gland near your kidney called phaeochromocytoma
- have severe problems with breathing
- have increased pressure on the brain, have just had a head injury or if you are unconscious
- are suffering from acute alcoholism
- are at risk from a blocked intestine
- have severe stomach cramps caused by a condition known as biliary colic
- are suffering from severe diarrhoea
- are pregnant or breast-feeding.

Warnings and precautions
Talk to your doctor before Diamorphine Injection is given if you:
- suffer from asthma (your doctor may decide to administer Diamorphine Injection if your asthma is controlled. However, you should not be given this medicine if you are having an acute asthma attack)
- suffer from bronchitis (an inflammation of the lining of the tubes in the lungs, resulting in coughing spells accompanied by thick phlegm and breathlessness) or emphysema (a lung condition which leaves you struggling for breath)
- suffer from cor-pulmonale (a type of heart failure)
- are severely obese
- have a severely deformed spine
- are suffering from mental illness brought on by an infection
- have liver problems
- have kidney problems
- have problems with your bile duct
- suffer from an enlarged prostate gland (in men) or have difficulty passing urine
- have an under-active thyroid or adrenal gland
- have low blood pressure
- are in a state of severe shock
- are very run down
- have bowel disease, such as Crohn's disease or ulcerative colitis
- suffer from convulsions (fits)
- are a child or elderly
- are feeling weak and feeble
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- feel you need to take more of Diamorphine Injection to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.
Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.
Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.
If any of the above apply to you, speak to your doctor or nurse before Diamorphine Injection is given to you.

Other medicines and Diamorphine Injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, tell your doctor if you are taking any of the following:
- monoamine oxidase inhibitors (MAOIs) such as moclobemide or phenelzine used in the treatment of depression. You must also tell your doctor if you have stopped taking any of these or related medicines in the last two weeks.
- tricyclic antidepressants, which are used in the treatment of depression
- tranquillising drugs or sleeping tablets such as diazepam, nitrazepam and temazepam.
- medicines used to treat mental illnesses, including schizophrenia (e.g. chlorpromazine, haloperidol).
- medicines used for diarrhoea (e.g. loperamide, kaolin).
- medicines which are used as premedication before operations and after heart attacks such as atropine.
- medicines used to treat nausea and vomiting, such as metoclopramide or domperidone
- mexiletine, used to control heart rhythm.
- cimetidine, used to treat stomach ulcers and indigestion
- ritonavir, used to treat HIV (a viral infection)

Diamorphine Injection with alcohol
You should not drink alcohol whilst being given Diamorphine Injection as it will increase its effects.

Pregnancy and breast-feeding
Do not take Diamorphine Injection if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.
If you use Diamorphine Injection during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
Do not take Diamorphine Injection while you are breastfeeding as diamorphine hydrochloride passes into breast milk and will affect your baby.

Driving and using machines
You may feel drowsy and confused when you are being given Diamorpine Injection so you should not drive or operate machinery. This medicine can affect your ability to drive.
Do not drive whilst taking this medicine until you know how this medicine affects you.
It may be an offence to drive if your ability to drive safely is affected. There is further information for patients who are intending to drive in Great Britain - go to http://www.gov.uk/drug-driving-law

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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Diamorphine Hydrochloride 5mg for Injection
Diamorphine Hydrochloride 10mg for Injection
Diamorphine Hydrochloride 30mg for Injection
Diamorphine Hydrochloride 100mg for Injection
Diamorphine Hydrochloride 500mg for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Diamorphine Hydrochloride 5mg for Injection
- Each ampoule contains 5mg of Diamorphine Hydrochloride.

Diamorphine Hydrochloride 10mg for Injection
- Each ampoule contains 10mg of diamorphine hydrochloride.

Diamorphine Hydrochloride 30mg for Injection
- Each ampoule contains 30mg of diamorphine hydrochloride.

Diamorphine Hydrochloride 100mg for Injection
- Each ampoule contains 100mg of diamorphine hydrochloride.

Diamorphine Hydrochloride 500mg for Injection
- Each ampoule contains 500mg of diamorphine hydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
A white to off-white, sterile, freeze-dried powder of Diamorphine Hydrochloride for reconstitution for injection.

4 CLINICAL PARTICULARS
4.1 Therapeutic Indications
Diamorphine may be used in the treatment of severe pain associated with surgical procedures, myocardial infarction or pain in the terminally ill and for the relief of dyspnoea in acute pulmonary oedema.

4.2 Posology and Method of Administration
Method of administration
Diamorphine may be given by the intramuscular, intravenous or subcutaneous routes. Glucose intravenous infusion is the preferred diluent, particularly when the drug is administered by a continuous infusion pump over 24 to 48 hours, although it is also compatible with sodium chloride intravenous infusion.
The dose should be suited to the individual patient.
Posology
Adults:
Acute pain: 5mg repeated every four hours if necessary (up to 10mg for heavier, well muscled patients) by subcutaneous or intramuscular injection. By slow intravenous injection, one quarter to one half the corresponding intramuscular dose.
Chronic pain: 5-10mg regularly every four hours by subcutaneous or intramuscular injection. The dose may be increased according to individual needs.
Myocardial infarction: 5mg by slow intravenous injection (1mg/minute) followed by a further 2.5mg to 5mg if necessary.
Acute pulmonary oedema: 2.5mg to 5mg by slow intravenous injection (1mg/minute).
Children and Elderly:
As diamorphine has a respiratory depressant effect, care should be taken when giving the drug to the very young and the elderly and a lower starting dose than normal is recommended.
Hepatic impairment:
A reduction in dosage should be considered in hepatic impairment.
Renal impairment:
The dosage should be reduced in moderate to severe renal impairment.
Debilitated patients:
A reduction in dosage should be considered in debilitated patients.
For concomitant illnesses/conditions where dose reduction may be appropriate see 4.4 Special Warnings and Precautions for Use.
Prior to starting treatment with opioids, a discussion should be held with patients to put in place a strategy for ending treatment with diamorphine hydrochloride in order to minimise the risk of addiction and drug withdrawal syndrome (see section 4.4).

4.3 Contraindications
Acute respiratory depression.
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Phaeochromocytoma (endogenous release of histamine may stimulate catecholamine release).
Biliary colic (see also biliary tract disorders, 4.4 Special Warnings and Precautions).
Coma. Raised intracranial pressure. Head injuries, as there is an increased risk of respiratory depression that may lead to elevation of CSF pressure. The sedation and pupillary changes produced may interfere with accurate monitoring of the patient
Acute alcoholism.
Diamorphine is also contra-indicated where there is a risk of paralytic ileus, or in acute diarrhoeal conditions associated with antibiotic-induced pseudomembranous colitis or diarrhoea caused by poisoning (until the toxic material has been eliminated).

4.4 Special Warnings and Precautions for Use
Morphine-like opioids should either be avoided in patients with biliary tract disorders or they should be given with an antispasmodic (use in biliary colic is a contraindication see 4.3 Contraindications).
Diamorphine should be given in reduced doses or with caution to patients with asthma or decreased respiratory reserve (including kyphoscoliosis, emphysema, severe obesity, cor pulmonale). Avoid use during an acute asthma attack (see 4.3 Contraindications).
Use with caution or in reduced doses in patients with toxic psychosis, CNS depression, myxoedema, prostatic hypertrophy or urethral stricture, severe inflammatory or obstructive bowel disorders, hypotension, shock, convulsive disorders, adrenal insufficiency or debilitated patients.
Care should be exercised in treating the elderly, children or debilitated patients and those with hepatic or renal impairment (see 4.2 Posology for dosage recommendations).
Palliative care - in the control of pain in terminal illness, these conditions should not necessarily be a deterrent to use.
Drug dependence, tolerance and potential for abuse
For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression).
Additional support and monitoring may be necessary when prescribing for patients at risk of opioid misuse.
A comprehensive patient history should be taken to document concomitant medications, including over-the-counter medicines and medicines obtained on-line, and past and present medical and psychiatric conditions.
Patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of pain control as initially experienced. Patients may also supplement their treatment with additional pain relievers. These could be signs that the patient is developing tolerance. The risks of developing tolerance should be explained to the patient.
Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else.
Patients should be closely monitored for signs of misuse, abuse, or addiction.
The clinical need for analgesic treatment should be reviewed regularly.
Drug withdrawal syndrome
Prior to starting treatment with any opioids, a discussion should be held with patients to put in place a withdrawal strategy for ending treatment with diamorphine.
Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take weeks to months.
The opioid drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.
If women take this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.
Hyperalgesia
Hyperalgesia may be diagnosed if the patient on long-term opioid therapy presents with increased pain. This might be qualitatively and anatomically distinct from pain related to disease progression or to breakthrough pain resulting from development of opioid tolerance. Pain associated with hyperalgesia tends to be more diffuse than the pre-existing pain and less defined in quality. Symptoms of hyperalgesia may resolve with a reduction of opioid dose.

4.5 Interaction with other Medicinal Products and other forms of Interaction
Alcohol: Alcohol may enhance the sedative and hypotensive effects of diamorphine.
Anti-arrhythmics: Diamorphine may delay the absorption of mexiletine.
Antidepressants, anxiolytics, hypnotics: Severe CNS excitation or depression (hypertension or hypotension) has been reported with the concomitant use of monoamine oxidase inhibitors (MAOIs) and pethidine. It is therefore possible that a similar interaction may occur with other opioid analgesics – avoid concomitant use and for two weeks after stopping MAOIs.
The depressant effects of diamorphine may be exaggerated and prolonged by tricyclic antidepressants, anxiolytics and hypnotics.
Antivirals: Plasma concentration of opioid analgesics (except methadone) is possibly increased by ritinovir. Opioids potentiate the effects of CNS depressants including tricyclic antidepressants, anxiolytics and hypnotics.
Antipsychotics: enhanced sedative and hypotensive effect. Antidiarrhoeal and antiperistaltic agents (such as loperamide and kaolin): concurrent use may increase the risk of severe constipation.
Antimuscarinics: The risk of severe constipation and/or urinary retention is increased by administration of antimuscarinic drugs (e.g. atropine).

3. How Diamorphine Injection should be given

- Diamorphine injection must be used immediately after preparation.
- The usual adult dose for treatment of acute or chronic pain is 5mg to 10mg every four hours, given by injection under the skin or into muscle or 1.25 to 5mg every four hours given directly into a vein for acute pain. The dose will be adjusted to suit your needs.
- For a heart attack, 5mg is usually given into a vein followed, if needed, by another 2.5 to 5mg.
- For fluid on the lungs, 2.5 to 5mg is given into a vein.
- If you are elderly, a child, are severely run down including feeling weak and feeble, or have liver and kidney problems the dose will be lower. You may also be given a reduced dose if you suffer from any of the conditions listed in section 2 entitled "Speak to your doctor before Diamorphine Injection is given if you:"
- Your doctor will decide the dose that is best for you. If you do not understand what you are being given, or are in any doubt, ask your doctor or nurse.

Your prescriber should have discussed with you, how long the course of treatment will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

If you miss a dose of Diamorphine Injection

If you think that an injection has been missed, speak to your doctor or nurse.

If treatment with Diamorphine Injection is stopped

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor or nurse immediately if you experience the following **serious** side effect:

- A severe allergic reaction, such as breathing difficulties, shock or low blood pressure. If you suffer such a reaction, you should not be given any more diamorphine. Your doctor will decide on the appropriate treatment for allergic reactions.

Difficulty in breathing and physical and psychological dependence are possible serious side effects.

It is possible that you could become dependent on diamorphine.

Other side effects include:

- drowsiness
- feeling sick or being sick
- constipation
- sweating.

Apart from constipation, these side effects tend to disappear with time.

- dizziness
- feeling faint on standing up
- small pupils (in the eye)
- blurred vision
- double vision or other changes in vision
- mental clouding or confusion
- mood changes
- feeling extremely happy for no particular reason
- imagining things (hallucinations)
- headache
- vertigo
- facial flushing
- dry mouth
- difficulty or pain in passing urine
- passing less urine than usual
- biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may spread towards your right shoulder)
- palpitations
- slower or faster pulse
- skin rash
- wheals or itching
- reduced sexual drive or impotence after long term use
- dependence and addiction (see section "How do I know if I am addicted?").

Drug Withdrawal

When you stop taking Diamorphine Injection, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Diamorphine Injection, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

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 systems listed below:

United Kingdom

Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diamorphine Injection

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

Store the ampoules below 25ºC. Keep the ampoule in its outer carton, in order to protect it from light.

Do not use Diamorphine Injection if the powder in the ampoule or resulting solution shows signs of discolouration.

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.

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

6. Contents of the pack and other information

What Diamorphine Injection contains

The active substance is diamorphine hydrochloride. There are no other ingredients present.

What Diamorphine Injection looks like and contents of the pack

The injection is a white to off-white, sterile, freeze dried powder for reconstitution for injection.

Diamorphine Injection is available in five strengths (5mg, 10mg, 30mg, 100mg, or 500mg of diamorphine hydrochloride) in packs of 5, 10 or 50 ampoules.

Not all strengths and pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder in UK: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product Name	Reference Number
Diamorphine Hydrochloride 5mg for Injection	29831/0062
Diamorphine Hydrochloride 10mg for Injection	29831/0063
Diamorphine Hydrochloride 30mg for Injection	29831/0064
Diamorphine Hydrochloride 100mg for Injection	29831/0061
Diamorphine Hydrochloride 500mg for Injection	29831/0060

This is a service provided by the Royal National Institute of Blind People.

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Motility stimulants: There may be antagonism of the gastrointestinal effects of domperidone and metoclopramide.

Cimetidine inhibits metabolism of opioid analgesics.

4.6 Fertility, pregnancy and lactation

Pregnancy

Regular use during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the neonate.

If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Administration during labour may depress respiration in the neonate and an antidote for the child should be readily available.

Breast-feeding

Administration to nursing women is not recommended as diamorphine may be secreted in breast milk and may cause respiratory depression in the infant.

4.7 Effects on Ability to Drive and Use Machines

Diamorphine causes drowsiness and mental clouding. If affected patients should not drive or use machines.

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988.

When prescribing this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you
- It is an offence to drive while under the influence of this medicine
- However, you would not be committing an offence (called 'statutory defence') if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
  - It was not affecting your ability to drive safely

4.8 Undesirable Effects

The most serious hazard of therapy is respiratory (see also 4.9 Overdose). The most common side effects are sedation, nausea and vomiting, constipation and sweating. Tolerance generally develops with long-term use, but not to constipation.

Other side effects include the following:

Anaphylaxis: Anaphylactic reactions following intravenous injection have been reported rarely.

Cardiovascular: orthostatic hypotension, facial flushing, palpitations, tachycardia, bradycardia.

Central Nervous System: dizziness, vertigo, mental clouding, confusion (with large doses), hallucinations, headache, mood changes including dysphoria and euphoria.

Gastrointestinal: dry mouth, biliary spasm.

Disorders of the eye: blurred or double vision or other changes in vision, miosis.

Sexual dysfunction: long term use may lead to a reversible decrease in libido or potency.

Skin: rash, pruritus, urticaria.

Urinary: urinary retention, difficulty with micturition, ureteric spasm, antidiuretic effect. Tolerance develops to the effects of opioids on the bladder.

Psychiatric disorders: drug dependence (see section 4.4).

General disorders and administration site conditions: drug withdrawal syndrome.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting systems listed below.

United Kingdom

Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

4.9 Overdose

Patients should be informed of the signs and symptoms of overdose and to ensure that family and friends are also aware of these signs and to seek immediate medical help if they occur.

a) Symptoms

The triad of respiratory depression, coma and constricted pupils is considered indicative of opioid overdosage with dilatation of the pupils occurring as hypoxia develops. Pulmonary oedema after overdosage is a common cause of fatalities among diamorphine addicts.

Other opioid overdose symptoms include cold, clammy skin, hypotension, bradycardia, circulatory failure, muscle flaccidity, severe weakness, severe nervousness or restlessness, confusion, severe dizziness, severe drowsiness, hallucinations, convulsions (especially in infants and children), rhabdomyolysis progressing to renal failure.

b) Treatment

Respiration and circulation should be maintained and the specific opioid antagonist, naloxone is indicated if coma or bradypnoea are present, using one of the recommended dosage regimens. Oxygen and assisted ventilation should be administered if necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Diamorphine is a narcotic analgesic which acts primarily on the central nervous system and smooth muscle. It is predominantly a central nervous system depressant but it has stimulant actions resulting in nausea, vomiting and miosis.

5.2 Pharmacokinetic Properties

Diamorphine is a potent opiate analgesic which has a more rapid onset of activity than morphine as the first metabolite, monoacetylmorphine, more readily crosses the blood brain barrier. In man, diamorphine has a half-life of two to three minutes. Its first metabolite, monoacetylmorphine, is more slowly hydrolysed in the blood to be concentrated mainly in skeletal muscle, kidney, lung, liver and spleen. Monoacetylmorphine is metabolised to morphine. Morphine forms conjugates with glucuronic acid. The majority of the drug is excreted via the kidney as glucuronides and to a much lesser extent as morphine.

About 7-10% is eliminated via the biliary system into the faeces.

Diamorphine does not bind to protein. However, morphine is about 35% bound to human plasma proteins, mainly to albumin. The analgesic effect lasts approximately three to four hours.

5.3 Preclinical Safety Data

There are no additional pre-clinical data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Water for Injections (Not detectable in the finished product).

6.2 Incompatibilities

Physical incompatibility has been reported with mineral acids and alkalis and with chlorocresol. Mixtures of diamorphine with cyclizine, haloperidol or dexamethasone may result in precipitation. Mixtures of diamorphine and metoclopramide may become discoloured and should be discarded. Specialised references should be consulted for specific compatibility information.

6.3 Shelf Life

Three years from date of manufacture

6.4 Special Precautions for Storage

Do not store above 25°C.

Keep container in the outer carton.

6.5 Nature and Contents of Container

Diamorphine Hydrochloride 5mg for Injection, Diamorphine Hydrochloride 10mg for Injection and Diamorphine Hydrochloride 30mg for Injection - 2ml Neutral glass ampoules, PhEur. Type 1. Diamorphine Hydrochloride 100mg for Injection, Diamorphine Hydrochloride 500mg for Injection - 5ml Neutral glass ampoules, PhEur. Type 1.

Ampoules are packed into cartons of 5, 10 or 50.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

The solution should be used immediately after preparation.

7 MARKETING AUTHORISATION HOLDER

United Kingdom:

Wockhardt UK Limited

Ash Road North, Wrexham, LL13 9UF, UK

8 MARKETING AUTHORISATION NUMBER(S)

Diamorphine Hydrochloride 5mg for Injection – PL 29831/0062

Diamorphine Hydrochloride 10mg for Injection - PL 29831/0063

Diamorphine Hydrochloride 30mg for Injection - PL 29831/0064

Diamorphine Hydrochloride 100mg for Injection - PL 29831/0061

Diamorphine Hydrochloride 500mg for Injection - PL 29831/0060

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/04/2007

10 DATE OF REVISION OF THE TEXT

November 2021

103917/7

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