

Package leaflet: Information for the patient

Diamorphine Hydrochloride BP 100 mg and 500 mg Lyophilisate for Solution for Injection

This medicine is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop having it suddenly.

Read all of this leaflet carefully, before you are given this injection.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any side effects not listed in this leaflet. See section 4.

Before being used, the powder in the ampoules will be mixed with a liquid to make a solution which will be given to you by injection. This is called Diamorphine Hydrochloride BP Injection in this leaflet.

What is in this leaflet

1. What Diamorphine Hydrochloride BP Injection is and what it is used for
2. What you need to know before you are given the injection
3. How the injection is given
4. Possible side effects
5. Storing the injection
6. Further information

1. What Diamorphine Hydrochloride BP Injection is and what it is used for

Diamorphine Hydrochloride BP Injection can be used to:

- relieve severe pain associated with surgery, a heart attack or a terminal illness, or
- relieve breathlessness caused by fluid in the lungs.

Diamorphine Hydrochloride BP Injection belongs to a class of medicines called opioids, which are 'pain relievers'. Opioids can cause addiction and you may get withdrawal symptoms if you stop having it suddenly. Your doctor should have explained how long you will be having it for, when it is appropriate to stop and how to do this safely.

2. What you need to know before you are given the injection

Diamorphine Hydrochloride BP Injection is not suitable for everyone.

Tell the doctor or nurse that you **must not** have the injection if you:

- are aware that you are **allergic** to diamorphine or any other opioid analgesic such as codeine
- have a **tumour** of the **adrenal gland** near your kidney
- have **severe problems** with **breathing** or suffer from **bronchitis** or **asthma**
- have **raised pressure** in your **brain**
- have recently been treated for **depression** with drugs called **monoamine oxidase inhibitors (MAOIs)**
- are **pregnant** or **breast-feeding**.

Talk to your doctor or nurse before having the injection if you:

- are ill or elderly
- have problems with your liver or kidneys
- have a head injury
- have mental illness
- have problems with your thyroid, adrenal glands, prostate, bladder or bowel
- have diarrhoea
- have a severely deformed spine.
- 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 more Diamorphine Hydrochloride BP 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 doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Having this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be having it for, when it is appropriate to stop and 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 doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop having 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 doctor will discuss with you gradually reducing your dose before stopping the medicine. It is important that you do not stop having the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Receiving higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Other medicines and Diamorphine Hydrochloride BP Injection

Before the doctor gives you the injection tell them if you are taking any of the following medicines:

- Drugs to treat depression or mental illness including phenothiazines or tricyclic antidepressants as well as monoamine oxidase inhibitors
- Tranquillisers or sleeping tablets
- Antimuscarinic drugs such as atropine
- Drugs to prevent vomiting such as metoclopramide or domperidone
- Cisapride which is used to stimulate the gut
- Selegiline, a drug used in Parkinson's disease
- An antibiotic called 4-quinolone
- Cimetidine, used to treat stomach ulcers and indigestion, or if
- You have been drinking alcohol.

Concomitant use of Diamorphine Hydrochloride BP Injection 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 Diamorphine Hydrochloride BP Injection 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.

Make sure you tell your doctor about any other medicines you are taking or have taken recently, including any bought from a chemist or another shop.

Pregnancy and breast-feeding

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

Driving and using machines

The injection may cause drowsiness and loss of concentration so you should not operate a machine or drive a vehicle if affected. The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while having this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - the medicine has been prescribed to treat a medical or dental problem and
 - you have been given it by the doctor or according to the information provided with the medicine and
 - it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while having this medicine.

3. How the injection is given

The doctor will prepare the injection by mixing the powder with a liquid. They will know how much to give you. You can have the injection either under the skin, or into a muscle, or directly into a vein (called intravenous infusion). Your doctor should have discussed with you how long the course of injections will last. They will arrange a plan for stopping treatment. This will outline how they will gradually reduce the dose until you stop having the medicine.

The usual doses for adults are:

To relieve pain 5 – 10 mg every 4 hours injected under the skin or into a muscle.

If the drug is given directly into a vein, you will be given one quarter or one half of this dose.

The dose may be increased if necessary.

Following a heart attack 5 mg directly into a vein, followed, if needed, by a further 2.5 – 5 mg.

For fluid in the lungs 2.5 – 5 mg directly into a vein.

The elderly, children or people with liver or kidney problems, may be given a lower starting dose.

If treatment with Diamorphine Hydrochloride BP Injection is stopped

If you want to stop having this medicine, discuss this with your doctor first. They will 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 having this medicine.

4. Possible side effects

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

Tell your doctor immediately if you experience the following **serious** side effect:

- breathing or circulation depression. Your breathing may become shallow or you may collapse.

Tell your doctor if you notice any of the following side effects:

- **Not known** (frequency cannot be estimated from the available data):
 - drowsiness, feeling or being sick, constipation, sweating
 - dizziness, constricted pupils (eye), confusion, difficulty in passing water, spasm of the bile duct, feeling faint on standing up, facial flushing, palpitations, mood changes, dry mouth, skin rash, itching, headache
 - dependence and addiction (see section “How do I know if I am addicted?”).

Drug Withdrawal

When you stop having Diamorphine Hydrochloride BP 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 having Diamorphine Hydrochloride BP Injection, it could be a sign that you have become addicted:

- You need to have the medicine for longer than advised by your doctor
- You feel you need to have more than the recommended dose
- You are having the medicine for reasons other than prescribed
- When you stop having the medicine you feel unwell, and you feel better once having the medicine again.

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

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 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. Storing the injection

- Do not store above 25°C. Keep the injection in the outer carton to protect it from light.
- This medicine should not be used after the expiry date on the carton or if the powder in the ampoule or the solution are discoloured.
- Diamorphine Hydrochloride BP Injection must be used immediately after the solution has been prepared.
- Diamorphine Hydrochloride BP Injection must be kept in a secure place out of the sight and reach of children.
- Diamorphine Hydrochloride BP is a Controlled Drug and must be stored and disposed of according to regulations.

6. Further information

Each 5 ml ampoule contains either 100 mg or 500 mg of the active ingredient, Diamorphine Hydrochloride BP, which is a white or off-white powder. The medicine is prepared for use by dissolving the powder in a liquid.

Each pack contains 5 glass ampoules.

Marketing Authorisation Holder

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