

**DepoDur<sup>®</sup>**  
**Morphine sulfate**  
**10 mg/mL Modified Release**  
**Suspension for Injection**

---

**Consumer Medicine Information**

---

**What is this leaflet?**

---

This leaflet answers some common questions about DepoDur modified release suspension for injection. It does not contain all of the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given DepoDur against the benefits they expect it will have for you. If you have any concerns about being given DepoDur, ask your doctor or the medical staff looking after you.

Keep this leaflet. You may need to read it again.

**What DepoDur is used for**

---

DepoDur modified release suspension for injection is used to provide pain relief immediately following a surgical operation (orthopaedic, abdominal, or pelvic).

The morphine sulfate in DepoDur will be released over time to provide pain relief for up to 48 hours, decreasing the need for other pain medication.

DepoDur contains the active ingredient, morphine sulfate. Morphine sulfate belongs to a group of medicines called opioids. These agents are used to relieve pain.

The inactive ingredients include cholesterol, triolein, tricapylin, dioleoylphosphatidylcholine,

dipalmitoylphosphatidylglycerol, sodium chloride, diluted (10%) hydrochloric acid, and water for injections.

Your doctor may have prescribed DepoDur for another use. Ask your doctor if you have any questions about why DepoDur has been prescribed for you.

The morphine in DepoDur can be addictive. Patients with a history of opioid or other substance abuse would be considered to be at greater risk of addiction or abuse. You should discuss this with your doctor.

**Before you are given DepoDur**

---

DepoDur modified release suspension for injection is not suitable for everyone.

**When you must not be given it**

You should not be given DepoDur if:

- You are allergic to morphine or any of the other ingredients listed at the end of this leaflet.
- You have symptoms of an allergic reaction to DepoDur which may include:
  - Shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
  - Swelling of the face, lips, tongue or other parts of the body
  - Rash, itching, hives or flushed, red skin
  - Dizziness or light headedness
- You are also given other intravenous or epidural opioid pain medication or epidural anaesthetics.
- You have any medical condition(s) that makes an epidural injection unsafe.
- You are also given long-acting opioids including long acting formulations of morphine sulfate, oxycodone, oxymorphone, methadone, fentanyl, or hydromorphone.
- You are undergoing day surgery or having surgery above the abdomen.

- You have poor or difficulty breathing, upper airway blockage, or severe asthma.
- You have low blood pressure or low blood flow.
- If you are under 18 years of age.
- Your small bowel is not working properly with severe pain in the stomach with bloating, gut cramps and vomiting.
- You have suspected or known head injury or increased pressure in the head.
- You will undergo vaginal labour and delivery. DepoDur can be given to women undergoing caesarean section after the umbilical cord has been clamped.
- You are breast-feeding. Small amounts of morphine sulfate are typically found in breast milk after administration of any morphine formulation.
- You are taking a medicine for depression called a “monoamine oxidase inhibitor” or have taken any in the last two weeks.
- Medical condition(s) that makes an epidural injection unsafe, such as an infection at the injection site, a blood infection or abnormal blood clotting.
- Opioid or other substance abuse.
- Seizure disorders.
- Biliary surgery or disorders of the biliary tract, including inflammation of the pancreas.
- Low activity of the adrenal gland.
- Conditions accompanied by low oxygen levels or high carbon dioxide levels.
- Debilitating conditions.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

DepoDur can occasionally cause your breathing to become too slow. This can be dangerous if unrecognised and untreated. Therefore it is mandatory for hospital staff to provide continuous monitoring and observation for 48 hours following administration of DepoDur even if the surgery has been cancelled, changed to a more minor procedure or if you are given other treatments for your pain.

Males being treated with DepoDur should use contraceptive measures, as the effect on sperm is not known at this time.

If you have not told your doctor about any of the above, tell him/her before you are given DepoDur.

An anaesthetist will inject Depodur in the space around the spinal cord (epidural). Depodur must not be given any other way.

If you are not sure whether you should be given this medicine, talk to your doctor.

### ***Before you are given it***

Tell your doctor if you have or have had any of the following medical conditions:

- Allergies.
- Severe problems with your breathing.
- Low blood pressure.
- Inflammatory bowel disorders.
- Enlarged prostate.
- Difficulty passing urine.
- Sleep apnoea.

### ***Taking other medicines***

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

Some medicines and DepoDur may interfere with each other. These include:

- Medicines used to produce calmness or help you to sleep.

- Local anaesthetics including anaesthetics given around the spinal cord.
- Medicines used for depression called monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment with MAOIs.
- Medicines that lower your blood pressure (antihypertensives such as clonidine).

These medicines may be affected by DepoDur, or may affect how well it works.

Avoid alcohol when using DepoDur.

---

### **How DepoDur is given**

---

A qualified and experienced anaesthetist (a type of doctor familiar with the practice of placing epidural catheters or needles and administering medication) will inject DepoDur in the space around the spinal cord (epidural space). DepoDur must not be given any other way.

If a local anaesthetic/adrenaline test dose is administered to rule out accidental intravenous or intrathecal placement of the catheter, DepoDur may be administered only after flushing the catheter followed by a 15-minute interval.

You will be continuously monitored and observed for 48 hours following administration of DepoDur.

### ***How much is given***

DepoDur may be used as supplied, but can also be diluted up to a volume of 5-mL.

Adults:

The recommended dose is 10 mg (this is also the maximum recommended dose).

Elderly (≥65 years):

The recommended dose is 7.5 mg (this is also the maximum recommended dose).

### ***Overdose***

As DepoDur is given to you in hospital under the supervision of a doctor, it is unlikely that you will receive an overdose.

The active pain relieving ingredient in DepoDur is morphine. Some people are more sensitive to morphine than others and require a small dose.

If you are given more DepoDur than you need to control your pain there is an antidote. An opioid antagonist can be administered to prevent the effects of the morphine sulfate in DepoDur. This may also reverse some of the pain killer effect.

---

### **While you are being given DepoDur**

---

#### ***Thing you must not do***

Do not take any other medicines, whether whether they are prescription or over-the-counter medicines, for forty-eight hours (48) after taking DepoDur unless they have been approved or recommended by a doctor that knows you were treated with DepoDur.

#### ***Things to be careful of***

Be careful driving or operating machinery until you know how DepoDur affects you. This medicine may cause dizziness, drowsiness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous within 48 hours of treatment.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

---

**Side Effects**

---

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with DepoDur. Like other epidurally-administered opioid medicines, DepoDur may have unwanted side effects, some of which may be serious.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

DepoDur, like all other morphine preparations, can sometimes cause you to feel sick (or even vomit). After receiving DepoDur, you may experience the following:

- Skin itching
- Skin redness and inflammation
- Fever
- Headache
- Constipation
- Dizziness
- Flatulence
- Rapid heart beat
- Difficulty sleeping
- Feeling of anxiety or panic.

You may also experience decreased sensitivity to stimulation from things such as light, touch or pain, or encounter abnormal sensations such as numbness, tingling or burning.

You may experience difficulty passing urine from the bladder (urinary retention). Importantly, you may develop poor or difficulty breathing, weakness, slowed heart beat and low blood pressure (dizziness when you stand up). In rare cases, you may develop extreme difficulty in breathing or have a heart attack. You will be monitored closely for such side effects by the medical staff looking after you.

You may be difficult to awaken, have dulled senses, feel more confused or less alert than usual or you may become unconscious.

Other side effect not listed above may also occur in some people, including:

- Sleepiness/drowsiness
- Lethargy
- High blood pressure
- Shallow breathing
- Passing less urine than is normal
- Nervousness
- Back pain
- Increase sweating
- Indigestion
- Bladder spasm
- Shaking during fever
- Low potassium levels in blood
- Low carbon dioxide levels in blood
- Low oxygen levels in blood
- Small bowel not working properly causing severe pain in the stomach with bloating, gut cramps and vomiting

If you notice any side effects either listed or not listed in this leaflet, please notify a member of the staff taking care of you.

---

**After using DepoDur**

---

**Storage**

DepoDur modified release suspension for injection will be stored at the hospital.

- Store DepoDur in its original packaging in a refrigerator where the temperature is between 2°C - 8°C. Avoid aggressive shaking.
- DepoDur may be stored at room temperature below 25°C for up to 30 days after which the vial **MUST** be discarded. Vials stored at room temperature may be separated from the carton, but should not be returned to a refrigerator.
- DepoDur should not be given if it is suspected to have been frozen. Freezing may adversely affect the

modified release mechanism of DepoDur.

- A freeze indicator visible through the top of the carton indicates if the DepoDur has been frozen. Vials from the carton should only be used if the solution in the bulb of the freeze indicator is clear. If the solution in the bulb is pink or purple, the DepoDur should be destroyed.
- DepoDur must be kept where children cannot reach it or see it.
- DepoDur should be used immediately after withdrawal from the vial. If storage is necessary after withdrawal, DepoDur should be held at 2-8°C for not more than 24 hours.
- DepoDur is for single-use in one patient on one occasion only. Discard any residue.

### ***Disposal***

Any unused medicine must be disposed appropriately by the medical staff.

---

### **Product description**

---

#### ***What DepoDur looks like***

DepoDur appears as a white to off-white homogeneous suspension (similar to skimmed milk) for injection. It is a sterile solution that contains no antimicrobial agent. DepoDur is for single use in one patient only.

DepoDur is supplied in cartons each containing five single-dose glass vials (Ph.Eur. type I amber glass), closed with ethylenetetrafluoroethylene (ETFE) stoppers and sealed with aluminium flip-off seals.

#### ***Ingredients***

Each vial contains 1 mL of DepoDur for a single injection. Each mL of suspension contains 10 mg morphine sulfate.

It also contains cholesterol, triolein, tricaprylin, dioleoylphosphatidylcholine, dipalmitoylphosphatidylglycerol, sodium chloride, diluted (10%) hydrochloric acid and water for injections.

#### ***Sponsor***

DepoDur is distributed in Australia by:

Orphan Australia Pty. Ltd.  
48 Kangan Drive  
Berwick, Victoria 3806  
www.orphan.com.au

Under licence from:  
Pacira Pharmaceuticals, Inc.  
10450 Science Center Drive  
San Diego, CA 92121  
USA

This leaflet was prepared in December 2007.

Australian Registration Number:  
AUST R 123620