# Actimorph 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg Orodispersible tablets

morphine sulfate

**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 possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Actimorph Orodispersible tablets are and what they are used for

The active substance of Actimorph Orodispersible tablets is morphine which belongs to a group of medicines called strong analgesics or 'painkillers' from the opioids group. This medicine has been prescribed by your doctor to relieve severe pain which can be adequately managed only with opioids.

## 2. What you need to know before you take Actimorph Orodispersible tablets

**Do not take Actimorph Orodispersible tablets**
- if you are allergic to morphine or any of the other ingredients of this medicine (listed in section 6);
- if the patient is a child under 6 months of age (see section "Children");
- if you have breathing problems, such as obstructive airways disease or respiratory depression. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- if you have severe bronchial asthma;
- if you have a head injury that causes a severe headache or makes you feel sick. This is because this medicine may make these symptoms worse or hide the extent of the head injury;
- if you have uncontrolled epilepsy;
- if you have recent onset liver disease;
- if you have a disease where the small bowel (part of your gut) does not function properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have sudden acute pain in your abdomen;
- if you are taking medicines containing buprenorphine, nalbuphine and pentazocine (substances which have properties similar to those of morphine and which may reduce the effects of morphine) as well as medicines containing naltrexone, nalmefene and sodium oxybate;
- if you are taking a type of medicine known as monoamine oxidase inhibitors, used as antidepressants (such as tranylcypromine, phenelzine, isocarboxazid, moclobemide, and linezolid), or if you have taken these medicines in the last two weeks.

**Warnings and precautions**
**Tolerance, dependence, and addiction**
This medicine contains morphine which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Actimorph 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 take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Actimorph 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 taking Actimorph, it could be a sign that you have become dependent or addicted:
- you need to take the medicine for longer than advised by your doctor
- you need to take more than the recommended dose
- 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 taking the medicine you feel unwell, and you feel better once taking 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 taking Actimorph).

Talk to your doctor or pharmacist before taking Actimorph Orodispersible tablets, especially:
- if you are dependent on opioids, or if you have a history of substance abuse;
- if you have breathing problems, such as impaired lung function or decreased respiratory capacity. Symptoms may include breathlessness and coughing;
- if you have a severe heart problem after a long-term lung disease (cor pulmonale);
- if you have a severe headache or are feeling dizzy, as it may indicate that the pressure in your skull is increased;
- if you have head or brain injuries;
- if you have disturbances of consciousness;
- if you have low blood pressure (hypotension, associated with low circulating blood volume (hypovolaemia);
- if you have prostate problems;
- if you have urinary tract constriction or colic of the urinary tract;
- if you have problems with your gallbladder;
- if you have a bowel obstruction or an inflammatory bowel disorder;
- if you have a tumour of the adrenal gland;
- if you have experienced weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be symptoms of low production of the hormone cortisol in the adrenal glands, and you may need to take a hormone supplement;
- if you have inflammation of the pancreas (which can cause severe pain in the abdomen and back);
- if you have an under-active thyroid gland (hypothyroidism), kidney or long-term liver problems, as you may need a lower dose;
- if you suffer from, or have ever suffered from epilepsy, seizures (fits);
- if you have a sickle cell disease and you take morphine, your doctor will closely monitor you due to a possible association with acute chest syndrome. Your doctor will closely monitor you in case of association with morphine.

Actimorph Orodispersible tablets should be used with caution before and after surgery (increased risk of intestinal paralysis or respiratory depression).

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Actimorph Orodispersible tablets:
- Increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or a change in strong analgesic ("painkiller"), (see section 2);
- Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take hormone supplement;
- Loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production;
- The most significant risk of opioid overdose is a flattening and slowing of breathing (respiratory depression);
- Constipation is common under a morphine treatment. Especially if you had problems with bowel movements before you started taking it, talk to your doctor.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with Actimorph treatment. Symptoms usually occur within the first 10 days of treatment. Tell your doctor if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Actimorph or other opioids. Stop using Actimorph and seek medical attention immediately, if you notice any of the following symptoms: blistering, widespread scaly skin or pus-filled spots together with fever.

Sleep-related breathing disorders
Actimorph Orodispersible tablets 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.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

You must only take the tablets by mouth. These tablets should never be dispersed and injected as this may lead to serious side effects, which may be fatal.

**Elderly people**
This medicine should be used with caution in the elderly (see section "How to take Actimorph Orodispersible tablets").

**Children**
Do not give this medicine to children under 6 months of age (see section "Do not take Actimorph Orodispersible tablets").

**Other medicines and Actimorph Orodispersible tablets**
Tell your doctor if you are taking, have recently taken or might take any other medicines.
This is especially important if you are taking or might take any other medicines mentioned below:
- rifampicin to treat e.g. tuberculosis. It may reduce the effect of morphine;
- concomitant use of Actimorph Orodispersible tablets and sedative medicines such as benzodiazepines or related medicines 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 Actimorph Orodispersible tablets 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;
- medicines which have a central, i.e. dampening effect on brain function or alcohol, it may increase the side effects of morphine;
- medicines to help you to sleep or stay calm (for example benzodiazepines, tranquillizers, hypnotics or sedatives);
- general anaesthetics;
- medicines to treat psychiatric disorders (such as phenothiazines);
- medicines to treat depression;
- muscle relaxants as morphine can increase the effect;
- medicines to treat high blood pressure;
- gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain);
- buprenorphine, nalbuphine or pentazocine, as well as naltrexone, nalmefene and sodium oxybate. Do not combine Actimorph Orodispersible tablets with these medicines. If you have any doubt, please talk to your doctor;
- other strong painkillers;
- medicines to treat depression, called monoamine oxidase inhibitors (MAOIs), or within two weeks of stopping their use (see section 2, "Do not take Actimorph Orodispersible tablets");
- medicines used to prevent or relieve the symptoms of an allergy (antihistamines);
- medicines to treat Parkinson's disease;
- certain types of medicines to stop you feeling or being sick;
- some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine;
- ritonavir to treat HIV;
- cimetidine to treat stomach ulcers, indigestion or heartburn.

**Actimorph Orodispersible tablets with alcohol**
Do not drink alcohol or take any medicines containing alcohol during treatment with this medicine.
Drinking alcohol during your treatment with this medicine may make you more drowsy or increase the risk of serious sides effects such as shallow breathing with the risk of stopping breathing and loss of consciousness.

**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
This medicine should not be used as much as possible in patients who are pregnant or nursing mothers, unless your doctor deems it absolutely necessary and considers the benefit for you to be significantly greater than the risk for the child.
Men and women of child-producing/child bearing potential must use reliable contraception while using Actimorph Orodispersible tablets.

If Actimorph Orodispersible tablets are used for a long time during pregnancy, there is a risk of the new-born child having withdrawal (abstinence) symptoms which should be treated by a doctor.
Withdrawal (abstinence) symptoms in babies born to mothers may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating.

Breast-feeding
You should not breast-feed during your treatment with this medicine as morphine is known to pass into breast milk.

**Driving and using machines**
Actimorph Orodispersible tablets may cause a number of side effects such as drowsiness which could affect your ability to drive or use machines (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking this medicine, or when changing to a higher dose. If you are affected, you should not drive or use machinery.

**Actimorph Orodispersible tablets contains benzyl alcohol, sodium and sulphites**
Actimorph 1 mg Orodispersible tablets: This medicine contains 0.1 microgram benzyl alcohol in each orodispersible tablet.
Actimorph 2.5 mg Orodispersible tablets: This medicine contains 0.25 microgram benzyl alcohol in each orodispersible.
Actimorph 5 mg Orodispersible tablets: This medicine contains 0.5 microgram benzyl alcohol in each orodispersible tablet.
Actimorph 10 mg Orodispersible tablets: This medicine contains 0.6 microgram benzyl alcohol in each orodispersible tablet.
Actimorph 20 mg Orodispersible tablets: This medicine contains 0.8 microgram benzyl alcohol in each orodispersible tablet.
Actimorph 30 mg Orodispersible tablets: This medicine contains 1 microgram benzyl alcohol in each orodispersible tablet.

Benzyl alcohol may cause allergic reactions.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breast feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially 'sodium-free'. Sulphites may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains morphine, which is listed as a doping substance. Its use can lead to positive results in anti-doping tests.

## 3. How to take Actimorph Orodispersible tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Actimorph, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Actimorph, in this section).

The dose will depend on the intensity of your pain and your previous history of the need for analgesics. When treating chronic pain, dose according to a fixed shedule should be given preference.

**Use in adults and adolescents over 16 years**
The usual starting dose is 10-20 mg every 4-6 hours. Your doctor will decide how many orodispersibles tablets you should take.

If you are still in pain while taking these tablets, talk to your doctor.

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

**Use in elderly patients (over 65 years)**
A reduction in dose is recommended in the elderly (dose reduction such as 2.5-5 mg every 4-6 hours).

**Use in patients with liver or kidney problems**
This medicine should be administered with particular care in patients with liver or kidney problems.

**Patients with a suspected delay in the gastrointestinal passage**
This medicine should be administered with particular care in patients with a suspected delay in the gastrointestinal passage.

**Use in children and adolescents**

**Use in adolescents: 13 to 16 years (40-60 kg)**
The usual starting dose is 5-20 mg every 4-6 hours.

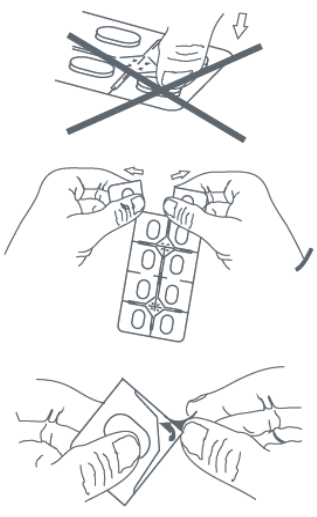
**Use in children: 6 to 12 years (18-40 kg)**
The usual starting dose is 5-10 mg every 4-6 hours.

**1 to 5 years (9-18 kg)**
The usual starting dose is 2.5-5 mg every 4-6 hours.

**over 6 months (6-9 kg)**
The usual starting dose is 1 mg every 4-6 hours.

**Method of administration**
- Oral use.
- Place the orodispersible tablet in the mouth. It will melt rapidly and can then be swallowed.
- Alternatively, you may place the orodispersible tablet in a spoon with a small quantity of water before giving it to your child or to people who have difficulties to swallow. It will rapidly melt enough to be swallowed more easily. This method of administration should be used in children below the age of 6 years.

**Opening instructions**
This medicine is available in peelable, child resistant perforated unit dose blisters.
Do not push the tablet through the foil.



Pull off a single dose by tearing along the perforated line on the blister and peel back the foil on the blister to expose the orodispersible tablet.

**Duration of treatment**
Do not take this medicine for longer than absolutely necessary.
Any change or interruption of treatment should be made as recommended by your doctor (see section "If you stop taking Actimorph Orodispersible tablets").

**If you take more Actimorph Orodispersible tablets than you should**
Call your doctor or hospital straight away as you may need emergency treatment in a hospital. An overdose can have consequences and can be fatal.
When seeking medical attention make sure that you take this leaflet and any remaining orodispersible tablets with you to show to the doctor.
People who have taken an overdose may have narrow pupils, feel very sleepy, decrease in heart rate, low blood pressure, drop of body temperature, have or get pneumonia from inhaling vomit or foreign matter (symptoms may include breathlessness, cough and fever).
People who have taken an overdose may also have breathing difficulties leading to unconsciousness or even death and/or suffer from a brain disorder (known as toxic leukoencephalopathy).
In more serious cases, circulatory insufficiency may occur and eventually lead to a deep coma.
Muscle damage up to muscle decay can occur (possibly resulting in kidney failure).

Under no circumstances should you place yourself in situations that require increased attention, such as driving.
The following measures in case of overdose are recommended until a doctor arrives:
Keep awake, give breathing commands, breathing aid.

**If you forget to take Actimorph Orodispersible tablets**
If you have taken a lower dose of Actimorph Orodispersible tablets than intended or have completely forgotten to take it, this will result in insufficient or no pain relief.
Do not take a double dose to make up for a forgotten dose.
Do not take two doses within 4 hours.
Continue the use in the recommended manner.

**If you stop taking Actimorph Orodispersible tablets**
Do not stop treatment with Actimorph Orodispersible tablets unless agreed with your doctor.
If you want to stop treatment with Actimorph Orodispersible tablets, ask your doctor how to slowly decrease the dose to avoid abstinence (withdrawal) symptoms.
Withdrawal symptoms may include body aches, tremors, diarrhea, abdominal pain, nausea, flu-like symptoms, rapid heartbeat and large pupils. Psychological symptoms are a pronounced feeling of dissatisfaction, anxiety and irritability.

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

## 4. Possible side effects

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

Stop using Actimorph and seek medical attention immediately if you notice any of the following symptoms:

Severe skin reaction with blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP).

The most serious side effect (uncommon), is a condition where you breathe more slowly or weakly than expected (respiratory depression). **Tell your doctor immediately** if this happens to you.

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

The most common side effects of morphine are nausea, vomiting, confusion, constipation and drowsiness.

There is a risk that you may become addicted or reliant on this medicine.

In patients treated with morphine, the following side effects have been reported:

**Very common: may affect more than 1 in 10 people**
- changes in mood, mostly elevated mood (euphoric), but also disgruntled mood (dysphoric),
- pupil constriction (narrowing of the pupil),
- constipation (your doctor can prescribe a laxative to overcome this problem),
- nausea, which stops after a certain time.

**Common: may affect up to 1 in 10 people**
- hypersensitivity,
- thinking disturbances,
- confusion, difficulty in sleeping,
- mood changes (usually reduced activity, but also increased activity or hyperexcitability),
- hallucinations,
- dizziness, headache,
- involuntary muscle contractions,
- somnolence,
- change in taste,
- vomiting (being sick),
- abdominal pain,
- dry mouth,
- loss of appetite,
- rash, hives or itchy skin,
- excessive sweating,
- difficulty in passing urine (notably in case of enlarged prostate or urethral stenosis),
- a feeling of unusual weakness,
- generally feeling unwell, tiredness.

**Uncommon: may affect up to 1 in 100 people**
- seizures, fits or convulsions,
- unusual muscle stiffness, muscle spasms,
- fainting/temporary loss of consciousness (syncope),
- tingling sensation or numbness in the limbs (paresthesia),
- a feeling of dizziness or 'spinning' (vertigo),
- rapid or irregular heartbeat (palpitations), pulse acceleration, pulse deceleration,
- facial flushing (redness of the face),
- low blood pressure, high blood pressure,
- lung œdema (fluid accumulation in the tissue and air spaces of the lungs), slow, shallow breathing (respiratory depression), respiratory discomfort (bronchospasm),
- a condition where the bowel does not work properly (ileus),
- increased liver enzymes (seen in a blood test),
- swelling of the hands, ankles or feet.

**Rare: may affect up to 1 in 1,000 people**
- increase in pancreatic enzymes, inflammation of the pancreas (pancreatitis),
- dull pain in the middle to upper right area of the abdomen (biliary colic).

**Very rare: may affect up to 1 in 10,000 people**
- overproduction of an antidiuretic hormone causing fluid retention, resulting in low level of sodium in blood, sluggishness, tiredness or confusion,
- decrease in libido,
- muscle tremors,
- blurred vision, double vision and eye trembling,
- difficulties in breathing,
- intestinal obstruction,
- dental diseases, but a causal connection to morphine treatment cannot be established,
- muscle cramps, increase in muscle tension,
- sharp pain in the lower back that radiates down the flank, which may be caused by kidney stones,
- erectile dysfunction,
- absence of menstrual periods,
- chills.

**Not known: frequency cannot be estimated from the available data**
- severe allergic reaction (anaphylactic reactions, anaphylactoid reactions),
- nightmares (more especially in the elderly),
- sedation,
- increased intracranial pressure,
- pain triggered by a stimulus that is normally painless (allodynia),
- increased sensitivity to pain (hyperalgesia – see also section 2),
- sleep apnoea (breathing pauses during sleep),
- light-headedness,
- heart failure,
- hot flushes (sudden feeling of warmth),
- decreased cough reflex,
- accumulation of water in the lungs after rapid dose increase (pulmonary œdema),
- medicine tolerance (when you no longer respond to a medicine in the way you did at first and takes a higher dose of the medicine to achieve the same effect),
- symptoms of withdrawal or dependence,
- withdrawal symptoms in babies born to mothers who have used Actimorph Orodispersible tablets in pregnancy (see section 2 "pregnancy, breastfeeding and fertility"),
- symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system e.g. severe upper abdominal possibly radiating to the back, nausea, vomiting or fever.

If this medicine is stopped abruptly, a withdrawal syndrome may appear: anxiety, irritability, chills, pupil dilation, hot flashes, sweating, tearing, runny nose, nausea, vomiting, abdominal pain, diarrhea, joint pain.

**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 Website: 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 Actimorph Orodispersible tablets

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
Store in the original package in order to protect from light.
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 protect the environment.

## 6. Contents of the pack and other information
## What Actimorph Orodispersible tablets contain

- The active substance is morphine sulfate.
Actimorph 1 mg Orodispersible tablets contain 1 mg of morphine sulfate.
Actimorph 2.5 mg Orodispersible tablets contain 2.5 mg of morphine sulfate.
Actimorph 5 mg Orodispersible tablets contain 5 mg of morphine sulfate.
Actimorph 10 mg Orodispersible tablets contain 10 mg of morphine sulfate.
Actimorph 20 mg Orodispersible tablets contain 20 mg of morphine sulfate.
Actimorph 30 mg Orodispersible tablets contain 30 mg of morphine sulfate.
- The other ingredients are: mannitol, hydroxypropyl cellulose, microcrystalline cellulose, crospovidone type A, acesulfame potassium, orange flavour (including benzyl alcohol, sodium, sulphites), silicon dioxide, magnesium stearate.

**What Actimorph Orodispersible tablets look like and contents of the pack**
Actimorph 1 mg Orodispersible tablets are round, convex, 5 mm of diameter, white tablets engraved "1" on one side and smooth on the other side.
Actimorph 2.5 mg Orodispersible tablets are round, convex, 7 mm of diameter, white tablets engraved "2.5" on one side and smooth on the other side.
Actimorph 5 mg Orodispersible tablets are round, convex, 8.5 mm of diameter, white tablets engraved "5" on one side and smooth on the other side.
Actimorph 10 mg Orodispersible tablets are round, convex, 10 mm of diameter, white tablets engraved "10" on one side and smooth on the other side.
Actimorph 20 mg Orodispersible tablets are round, convex, 11 mm of diameter, white tablets engraved "20" on one side and smooth on the other side.
Actimorph 30 mg Orodispersible tablets are round, convex, 12 mm of diameter, white tablets engraved "30" on one side and smooth on the other side.

Actimorph Orodispersible tablets are available in packs of 56 orodispersible tablets.

**Marketing Authorisation Holder and Manufacturer**

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
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Ethypharm UK - email: medinfo@ethypharm.com.

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