

ORAMORPH ORAL SOLUTION

Contains the active ingredient Morphine sulphate pentahydrate

Consumer Medicine Information

WARNING:

Limitations of use

ORAMORPH should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

ORAMORPH poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

ORAMORPH can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting ORAMORPH and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using OROMORPH

Using ORAMORPH with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using ORAMORPH.

What is in this leaflet

Please read this leaflet carefully before you start using ORAMORPH

This leaflet answers some common questions about ORAMORPH. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ORAMORPH against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

ORAMORPH contains the active ingredient morphine sulfate pentahydrate. Morphine belongs to a group of medicines called opioid analgesics.

ORAMORPH is used to provide the short-term management of severe pain for which other treatment options have failed or are otherwise inappropriate to provide sufficient management of pain.

Your doctor may have prescribed ORAMORPH for another reason.

Ask your doctor if you have any questions about why ORAMORPH has been prescribed for you.

This medicine is available only with a doctor's prescription.

Use in children

ORAMORPH should not be administered to neonates (28 days any younger) or premature infants. The safety and effectiveness of this medicine has not been established in these groups.

Before you take this medicine

When you must not take it

Do not use ORAMORPH if:

- you are allergic to morphine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have acute breathing difficulties such as bronchitis or asthma
- you have severe abdominal pain with bloating, cramps or vomiting
- you have a condition where your small bowel does not work properly
- you take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks
- you are pregnant or in labour
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

If you are not sure whether you should start using ORAMORPH, talk to your doctor.

Before you start to take it

Tell your doctor or pharmacist if:

- You have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- are severely drowsy, have a reduced level of consciousness or are feeling faint or dizzy upon standing
- have heart problems or heart disease
- have low blood pressure
- have chronic lung disease
- suffer from sleep apnoea (temporarily stopping breathing while you sleep)
- have just drunk a large amount

of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol

- suffer from convulsions, fits or seizures
- have a head injury, brain tumour or increased pressure in your head
- are about to have surgery, had recent gastrointestinal surgery or have had other surgery in the last 24 hours
- have chronic liver or kidney disease
- have increased prostate size or difficulty passing urine
- have problems with your gall bladder
- have problems with or recent surgery of your bile duct
- have inflammation of the pancreas
- have adrenal glands which are not working properly
- have an underactive thyroid gland
- have a severe mental condition involving losing contact with reality or an inability to think clearly
- have an addiction or history of abuse of alcohol, opioids or other drugs.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under 'Possible Side Effects'

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ORAMORPH given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Low levels of opioid analgesics have been detected in human milk.

Addiction

You can become addicted to ORAMORPH even if you take it exactly as prescribed. ORAMORPH may become habit forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking ORAMORPH. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking ORAMORPH suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to ORAMORPH may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea

- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

If you have not told your doctor about any of the above, tell them before you start using ORAMORPH.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking ORAMORPH.

Some medicines may interfere with ORAMORPH and affect how it works.:

Using ORAMORPH with medicines that can make you feel drowsy may result in severe drowsiness, decreased awareness, breathing problems, coma and death. These medicines include:

- sleeping tablets and other sedatives (including benzodiazepines and barbiturates)
- gabapentinoids
- cannabis
- antihistamines
- anxiolytics
- general anaesthetics
- antiemetics
- antidepressants (including tricyclic antidepressants)
- antipsychotics (including phenothiazines)
- neuroleptics
- beta-blockers (medicines used to treat high blood pressure)
- other opioids

- alcohol.

ORAMORPH may enhance the action of neuromuscular blocking agents (medicines used to relax muscles) and affect your breathing.

ORAMORPH may increase the anticoagulant activity of coumarin and other anticoagulants (medicines used to prevent blood clots).

ORAMORPH should not be used if you are taking non-selective monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ORAMORPH.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ORAMORPH.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

The label should be carefully read.

How much to take

Your doctor will tell you how much to take.

Follow the instructions provided and use ORAMORPH until your doctor tells you to stop.

If you do not understand the instructions on the packaging of this medicine, ask your doctor or pharmacist for help.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Measure the dose accurately with a medicine measure. Using a medicine measure such as a measuring glass or oral syringe, will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

Wipe the neck of the bottle and the cap after use to assist with re-opening.

When to take it

Take ORAMORPH every 4 hours or as directed by your doctor.

Take ORAMORPH at about the same time each day.

ORAMORPH can be taken before or after food, but try to take it the same way every time.

How long to take it

Keep using ORAMORPH as directed until your doctor tells you to stop.

If you forget to take it

If you are taking regular doses of ORAMORPH, you should take it at the same time each day. If you miss your dose at the usual time, you may take ORAMORPH as soon as you remember or think you need it.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of getting unwanted side effects including severe drowsiness, decreased awareness, breathing problems, coma and death.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, call triple one (111) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used ORAMORPH that was prescribed for you. If someone takes an overdose, they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits.

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) for

advice, or go to Accident and Emergency at the nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

While you are taking this medicine

Things you must do

Take this medicine exactly as your doctor has prescribed.

Call your doctor straight away if you:

- become pregnant
- feel your pain is getting worse.

Tell all your doctors, dentists and pharmacists that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking ORAMORPH.

Things you must not do

Do not stop using this medicine suddenly. If you stop taking ORAMORPH suddenly, your pain may worsen and you may experience withdrawal symptoms.

Do not use this medicine to treat any other complaints unless your doctor says to.

Do not give ORAMORPH to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how ORAMORPH affects you.

ORAMORPH may cause drowsiness or impair mental and/or physical ability in some people.

Tell your doctor if you drink alcohol.

Alcohol may make you feel more sleepy, and could increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Possible side effects

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

If you experience any of the side effects listed below and they worry you speak to your doctor

Gastrointestinal and urinary related:

- constipation
- nausea or vomiting
- difficulty urinating

Neurological and behaviour related

- dizziness
- drowsiness
- headache

Allergy related

- Sweating

Serious side effects

If you experience any of these serious side effects call your doctor

straight away or got straight away to the emergency department at your nearest hospital.

Breathing related:

- difficulty breathing or shallow breathing

Neurological and behavior related:

- light headedness, fainting or dizziness especially when standing up
- changes in mood
- drowsiness or feeling extremely sedated
- feeling disorientated and having nightmares

Heart-related:

- Slow or noticeable heartrate

Gastrointestinal and urinary related:

- severe stomach pain with nausea or vomiting
- difficulty urinating

Allergy related:

- shortness of breath, swelling or the face, lips, tongue or other parts of the body

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Ask your doctor or pharmacist if you do not understand anything in this section.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Storage and disposal

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store any medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, your pharmacist can dispose of the remaining medicine safely.

ORAMORPH oral solution only lasts for 3 months once the bottle has been opened as long as the expiry date has not passed. Dispose of any remaining solution once the 3 months has passed.

To help you remember, write the date of opening on the label.

Product description

What it looks like

ORAMORPH 10mg/5mL oral solution is a clear, nearly colourless liquid.

Available in

- bottles of 100 mL.

Ingredients

ORAMORPH oral solution contains 10mg or morphine sulfate pentahydrate per 5mL. It also contains the following inactive ingredients:

- Sucrose
- Corn syrup
- Methyl parahydroxybenzoate (E218)
- Propyl parahydroxybenzoate (E216)
- Ethanol (96%)
- Water

This medicine is lactose and gluten free.

Sponsor

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