

Package leaflet: Information for the user

Oramorph® Oral Solution 10 mg/5 ml (morphine sulfate)

This medicine contains morphine sulfate 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 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 symptoms 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 ORAMORPH Oral Solution is and what it is used for
2. What you need to know before you take ORAMORPH Oral Solution
3. How to take ORAMORPH Oral Solution
4. Possible side effects
5. How to store ORAMORPH Oral Solution
6. Contents of the pack and other information

1. What ORAMORPH Oral Solution is and what it is used for

The name of your medicine is ORAMORPH Oral Solution 10 mg/5 ml (called ORAMORPH in this leaflet).

- This medicine has been prescribed to you for relief of severe pain
- It contains the active substance morphine sulfate, 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 take ORAMORPH Oral Solution

Do not take ORAMORPH:

- if you are allergic (hypersensitive) to morphine sulfate or any of the other ingredients of ORAMORPH (listed in Section 6)
- if you have problems with your lungs or breathing such as ‘hypoventilation’ or ‘Chronic Obstructive Pulmonary Disease’ (COPD)
- if you are having an asthma attack
- if you have sudden or recent liver problems
- if you have recently had a head injury
- if you have something called ‘phaeochromocytoma’. This is a rare tumour which is not malignant
- if you have fits (convulsions) or increased pressure inside your skull
- if the person taking the medicine is in a deep and prolonged unconscious state (coma)
- if you are addicted to alcohol or have recently consumed large amounts of alcohol
- if you are taking or have in the last two weeks taken medication to treat depression such as monoamine-oxidase inhibitors (MAOIs)
- if you have paralytic ileus (loss of intestinal movement)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

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 ORAMORPH 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 ORAMORPH 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 ORAMORPH, 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 ORAMORPH).

Take special care with ORAMORPH

Check with your doctor or pharmacist before taking your medicine:

- if you are pregnant, trying to become pregnant or if you are breast-feeding
- if you have had an operation within the last 24 hours
- if you have a particular lung problem that causes shortness of breath called emphysema or you have heart failure
- if you have shock (circulatory failure)
- if you have asthma
- if you have gall bladder problems
- if you have long term (chronic) liver or kidney problems
- if you are a man who has prostate problems
- if you have an under-active thyroid gland or swelling of your skin (myxoedema)
- if you have an unusually curved spine (kyphoscoliosis)
- if you have bowel problems
- if you have an under-active adrenal gland (adrenocortical insufficiency)
- if you are very overweight
- if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking ORAMORPH.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with ORAMORPH 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 ORAMORPH or other opioids. Stop using ORAMORPH 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

ORAMORPH 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking ORAMORPH.

Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while you are taking ORAMORPH

- Increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your prescriber will decide whether you will need a change in dose or a change in strong analgesic (“painkiller”)
- Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of your adrenal glands producing too little of a hormone called cortisol, and you may need to take a hormone supplement
- Loss of libido (sex drive), difficulty getting an erection, menstrual periods stopping. This may be because of your body producing less sex hormones
- You feel you need to take more of ORAMORPH 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.

Other medicines and ORAMORPH

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because ORAMORPH can affect the way some other medicines work. Also some other medicines can affect the way ORAMORPH works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to help you sleep, make you feel less anxious or calm you down such as tranquilisers, hypnotics, sedatives, antipsychotics or tricyclic antidepressants
 - o Taking ORAMORPH together with 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, taking ORAMORPH together with these types of medicines should only be considered when other treatment options are not possible. However if your doctor does prescribe ORAMORPH together with sedative medicines the dose and duration of taking the treatments together should be limited by your doctor.
 - o 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 if you experience these symptoms
- Anaesthetics - used during operations
- Domperidone, metoclopramide or phenothiazine - medicines for feeling sick (nausea) and being sick (vomiting)
- Mexiletine and esmolol - for controlling heart rhythm
- Ritonavir - for HIV infections
- Cimetidine - for stomach ulcers, indigestion or heartburn
- Monoamine oxidase inhibitors (MAOIs) – for depression
- Rifampicin - used to treat tuberculosis and other infections
- Gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain)
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with ORAMORPH

ORAMORPH with alcohol

You should avoid alcohol whilst taking this medicine.

Pregnancy and breast-feeding

Do not take ORAMORPH 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 ORAMORPH during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take ORAMORPH while you are breast-feeding as morphine sulfate passes into breast milk and will affect your baby.

This medicine contains ethanol (alcohol). See section "ORAMORPH contains sucrose, corn syrup (contains glucose), ethanol, methyl parahydroxybenzoate and propyl parahydroxybenzoate" for information about the alcohol contained in ORAMORPH.

Operations and anaesthetics

Tell your doctor or pharmacist if you are due to have an operation or an anaesthetic or if you have had an operation or an anaesthetic within the last 24 hours.

Driving and using machines

You may feel drowsy while taking this medicine. If this happens, do not drive or use any tools or machines.

Additional information for patients in the UK:

- Do not drive while taking 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:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o It was not affecting your ability to drive safely

This medicine contains ethanol (alcohol). See section “ORAMORPH contains sucrose, corn syrup (contains glucose), ethanol, methyl parahydroxybenzoate and propyl parahydroxybenzoate” for information about the alcohol contained in ORAMORPH.

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

ORAMORPH contains sucrose, corn syrup (contains glucose), ethanol, methyl parahydroxybenzoate and propyl parahydroxybenzoate

This medicine contains:

- **Ethanol (Alcohol):** This medicine contains 810 mg of alcohol (ethanol) in each 10 ml, which is equivalent to 81 mg/ml (10% v/v). The amount in 10 ml of this medicine is equivalent to 20 ml beer or 8 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable.

It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medication.

- **Sucrose and glucose:** This product contains 3 g sucrose in each 10 ml dose. This product also contains 1 g corn syrup, which contains glucose, in each 10 ml dose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. May be harmful to the teeth.
- **Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216):** These may cause allergic reactions in some people that could occur some time after taking this medicine. The signs may include swelling of the mouth and face, sudden breathing difficulties and your blood pressure being lower than normal

3. How to take Oramorph Oral Solution

Always take this medicine exactly as your doctor 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 ORAMORPH, 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 ORAMORPH, in this section).

Taking this medicine

- Take this medicine by mouth only
- Always use a 5 ml plastic spoon or another suitable measuring device to measure your dose
- Such devices are available from your pharmacist

Do not drink directly from the bottle as this may result in you taking the incorrect dose (too little or too much). Taking too much may result in an overdose with potential for serious consequences including unconsciousness and even death.

How much to take

Your doctor will decide the amount of medicine to give you.

Use in adults

- The most that should be taken is 5 to 10 ml (one to two 5 ml spoons) every four hours

Use in children and adolescents

Children 13 to 18 years

- The most that should be taken is 2.5 to 10 ml (half to two 5 ml spoons) every four hours

Children 6 to 12 years

- The most that should be taken is 2.5 to 5 ml (half to one 5 ml spoon) every four hours

Children 1 to 5 years

- The most that should be taken is 2.5 ml (half a 5 ml spoon) every four hours

Children under 1 year

- Do not give this medicine to children under 1 year

Being given more or less of this medicine

- For some people, it may be necessary for the doctor to give a higher dose
- For other people (for example the elderly, people with kidney or liver problems, an underactive adrenal or thyroid gland or prostate problems, and people that should not be sedated) the doctor may decide to use a lower dose

Your body may get used to the medicine (tolerance)

- Do not take more than your doctor has prescribed
- If you have been taking your medicine for some time you may find that it does not seem to be working as well as it did. If this happens, talk to your doctor

If you take more ORAMORPH than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you take more than you should, the following effects may happen:

- The black circle in the centre of your eyes (pupil) gets smaller
- You breathe more slowly
- You have low blood pressure

People who have taken an overdose may also get pneumonia from inhaling vomit or foreign matter, symptoms of this may include breathlessness, cough and fever.

In more severe cases, very high doses could cause your blood circulation and breathing to slow down and cause unconsciousness for a long time, or even death. In children a high dose may cause fits (convulsions).

If you forget to take ORAMORPH

- If you forget a dose, take it as soon as you remember it and take your next dose at the usual time
- If it is nearly time for the next dose, skip the missed dose. This is because the time between doses should be at least 4 hours

- Do not take a double dose to make up for a forgotten dose

If you stop taking ORAMORPH

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.

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. The following side effects may happen with this medicine, their frequency is not known:

Allergic reactions

If you have a severe allergic reaction, stop taking this medicine and see a doctor straight away. Signs may include swelling of the mouth and face, difficulty breathing, dizziness and skin reactions such as rash and itching.

Tell your doctor straight away if you notice the following side effects.

You may need urgent medical treatment:

- Having a headache. This could be a sign of increased pressure inside your skull
- Feeling dizzy or unsteady when you stand up. This could be a sign of a temporary fall in blood pressure (orthostatic hypotension)
- Shallow breathing, with a slow heartbeat (bradycardia) and cold clammy skin
- Feeling restless, irritable or having changes in your mood
- Stomach pain caused by spasm (cramps) of the tubes that carry urine to the bladder or bile to the intestines
- Difficulty breathing (not linked to an allergic reaction)
- Dry mouth or sweating
- Seeing or hearing things that are not there (hallucinations) or feeling confused
- Increased sensitivity to pain
- Dependence and addiction (see section “How do I know if I am addicted”)
- 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).

Drug Withdrawal

When you stop taking ORAMORPH, 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 ORAMORPH, 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

Other possible side effects

- Feeling sick (nausea) or being sick (vomiting)
- Constipation, which can be treated with appropriate laxatives
- Difficulty in passing water (urine)
- Feeling drowsy
- Flushing of your face
- Your heart rate getting faster (tachycardia) or slower (bradycardia) or fast and uneven (palpitations)
- Lower body temperature (hypothermia)
- Lowered sex drive or erection problems
- Muscles feeling tense
- The black circle in the centre of your eyes (pupil) getting smaller (miosis)
- Sleep apnoea (breathing pauses during sleep)
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system, e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

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:

United Kingdom

Yellow Card Scheme

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

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Oramorph Oral Solution

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 bottle label and the carton. The expiry date refers to the last day of that month.

Do not store ORAMORPH above 25°C. Store in the original container in order to protect from light.

Please return any remaining medicine to your pharmacist 3 months after first opening.

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 ORAMORPH contains

- The active substance is morphine sulfate. Each 5 ml contains 10 mg of morphine sulfate
- The other ingredients are alcohol (ethanol), corn syrup, sucrose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and purified water

What ORAMORPH looks like and contents of the pack

ORAMORPH is a solution and is available in bottles of 100, 250, 300 and 500 ml. The bottles come in cartons.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Glenwood GmbH Pharmazeutische Erzeugnisse
Arabellastr.17
81925 Munich
Germany

Manufacturer:

Istituto De Angeli S.r.l.
Località Prulli Di Sotto n. 103/C
50066 Reggello (FI)
Italy

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