**Package leaflet: Information for the user**

**Oramorph® Concentrated Oral Solution 20 mg/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.**

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. 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.
4. 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 Concentrated Oral Solution is and what it is used for
2. What you need to know before you take ORAMORPH Concentrated Oral Solution
3. How to take ORAMORPH Concentrated Oral Solution
4. Possible side effects
5. How to store ORAMORPH Concentrated Oral Solution
6. Contents of the pack and other information
7. **What ORAMORPH Concentrated Oral Solution is and what it is used for**

The name of your medicine is ORAMORPH Concentrated Oral Solution 20 mg/ml (called ORAMORPH Concentrated 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

1. **What you need to know before you take ORAMORPH Concentrated Oral Solution**

**Do not take ORAMORPH Concentrated:**

* if you are allergic (hypersensitive) to morphine sulfate or any of the other ingredients of ORAMORPH Concentrated (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 Concentrated 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 Concentrated 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 Concentrated, 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 Concentrated).

**Take special care with ORAMORPH Concentrated**

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 Concentrated.

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

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

* 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 Concentrated 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 Concentrated**

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 Concentrated can affect the way some other medicines work. Also some other medicines can affect the way ORAMORPH Concentrated 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
  + Taking ORAMORPH Concentrated 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 Concentrated together with these types of medicines should only be considered when other treatment options are not possible. However if your doctor does prescribe ORAMORPH Concentrated together with sedative medicines the dose and duration of taking the treatments together 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 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 Concentrated

**ORAMORPH Concentrated with alcohol**

You should avoid alcohol whilst taking this medicine.

**Pregnancy and breast-feeding**

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

Do not take ORAMORPH Concentrated while you are breast-feeding as morphine sulfate passes into

breast milk and will affect your baby.

**Operations and anaesthetics**

Tell your doctor or pharmacist if you are due to have an operation or 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:

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

* 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:
  + The medicine has been prescribed to treat a medical or dental problem and
  + You have taken it according to the instructions given by the prescriber or in 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 taking this medicine.

**ORAMORPH Concentrated contains amaranth, sodium benzoate and sodium**

This medicine contains amaranth. This may cause allergic reactions including asthma. Allergy is more

common in people who are allergic to aspirin.

This medicine also contains 1 mg sodium benzoate (E211) in each 1 ml.

This medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially ‘sodium-free’.

1. **How to take Oramorph Concentrated 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 Concentrated, 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 Concentrated, in this section).

**Taking this medicine**

* Take this medicine by mouth only
* Measure the exact dose using the supplied dosing syringe and adaptor
* Open the bottle and put the adaptor onto the top of the open bottle neck by pressing. Make sure it is fixed well in place
* Insert the syringe into the adaptor opening. Make sure the syringe is tightly inserted. Turn the bottle upside down and draw out the required amount of ORAMORPH Concentrated
* You may prefer to add your dose to a soft drink. If you do this, it should be swallowed immediately after mixing. Do not leave unattended.

The plastic adaptor should remain in the bottle after first use. The bottle cap should be replaced

after use.

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 0.5 to 1 ml (10-20 mg) every four hours

**Use in children and adolescents**

**Children 13 to 18 years**

• The most that should be taken is 0.25 to 1 ml (5-20 mg) every four hours

**Children 6 to 12 years**

• The most that should be taken is 0.25 to 0.5 ml (5-10 mg) every four hours

**Children 1 to 5 years**

• The most that should be taken is 0.25 ml (5 mg) 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 Concentrated 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 or 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 Concentrated**

* 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 Concentrated**

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.

1. **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 Concentrated, 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 Concentrated, 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.

1. **How to store Oramorph Concentrated 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 Concentrated above 25°C. Store in the original container in order to protect from light.

Please return any remaining medicine to your pharmacist 4 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.

1. **Contents of the pack and other information**

**What ORAMORPH Concentrated contains**

1. The active substance is morphine sulfate. Each ml contains 20 mg of morphine sulfate
2. The other ingredients are disodium edetate, sodium benzoate (E211), citric acid, amaranth (E123) and purified water

**What ORAMORPH Concentrated looks like and contents of the pack**

ORAMORPH Concentrated is available in bottles of 30 ml and 120 ml. A dosing syringe and bottle

adaptor are included for measuring the correct dose. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:**

Glenwood GmbH Pharmazeutische Erzeugnisse

Arabellastr.17

81925 Munich

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**Manufacturer:**

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**This leaflet was revised in October 2023**