

PACKAGE LEAFLET: INFORMATION FOR THE USER

Morphine 10mg/5ml Oral Solution

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 are given 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, please ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is In this leaflet:

1. What Morphine Oral Solution is and what it is used for
2. What you need to know before you take Morphine Oral Solution
3. How to take Morphine Oral Solution
4. Possible side effects
5. How to store Morphine Oral Solution
6. Contents of the pack and other information

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

This medicine has been prescribed for you for the relief of severe pain.

It contains 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 are given Morphine Oral Solution

Do not take Morphine Oral Solution if:

- you are allergic (hypersensitive) to Morphine sulfate or any of the ingredients of this medicine (listed in section 6).
- you have problems with your lungs or breathing such as 'hypoventilation' or 'Chronic Obstructive Pulmonary Disease' (COPD)
- you are having an asthma attack
- you have recently had a head injury
- you are addicted to alcohol or have recently consumed large amount of alcohol
- you have fits (convulsions) or increased pressure inside your skull
- you have sudden or recent liver problems
- you have paralytic ileus (loss of intestinal movement)
- you are taking or have in the last two weeks taken medication to treat depression such as Monoamine-Oxidase Inhibitors (MAOI's) (see 'Taking other medicines')
- you have something called 'phaeochromocytoma'. This is a rare tumour which is not malignant
- the person taking this medicine is in a deep and prolonged unconscious state (coma)

Do not take this medicine if any of the above applied 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 Morphine Oral Solution 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 Morphine Oral Solution 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 Morphine Oral Solution, 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 Morphine Oral Solution)

Warnings and precautions

Talk to your doctor or pharmacist before taking Morphine Oral Solution if:

- you are pregnant, trying to become pregnant or if you are breast-feeding
- You have a particular lung problem that causes shortness of breath called emphysema
- you are a man who has prostate problems
- you have an under-active adrenal gland (adrenocortical insufficiency)
- you have asthma
- you have gall-bladder problems
- you have long term (chronic) liver or kidney problems
- you have an under-active thyroid gland or swelling of your skin (myxoedema)
- you have had an operation in the last 24 hours
- you are extremely overweight
- your spine is unusually curved (kyphoscoliosis)
- you have shock (circulatory failure)
- you suffer from bowel problems
- you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- you feel you need to take more Morphine oral Solution to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or

006142000000

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.

Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while taking Morphine Oral Solution:

- Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenal 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.

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

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

Morphine Oral Solution 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.

Other medicines and Morphine Oral Solution

Tell your doctor if you are taking or have recently taken

any other medicines, including those obtained without prescription. This includes medicine that you buy without a prescription and herbal medicines. This is because Morphine Oral Solution can affect the way some other medicines work. Also some other medicines can affect the way Morphine Oral Solution works.

Morphine Oral Solution must not be used with drugs used to treat severe depression, such as phenelzine or moclobemide, or if you are within 2 weeks of discontinuing them. These drugs are known as Monoamine Oxidase Inhibitors (MAOI's).

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, anaesthetics, hypnotics, sedatives, antipsychotics, tricyclic antidepressants (clomipramine) and alcohol
- CNS depressants (drugs that act on the brain to cause drowsiness)
- medicines for controlling heart rhythm such as esmolol and mexiletine
- medicines to treat stomach ulcers, indigestion or heartburn such as cimetidine
- medicines for feeling sick (nausea) and being sick (vomiting) such as domperidone, metoclopramide or phenothiazide
- medicines to treat HIV infections such as ritonavir
- medicines used to treat fungal infections such as voriconazole
- medicines to treat epilepsy and long lasting pain caused by damage to the nerves such as gabapentin
- medicines to treat tuberculosis and other infections such as Rifampicin
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with opium
- Gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain).
- Concomitant use of Morphine Oral solution and sedative medicines such as benzodiazepines or related drugs 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 Morphine Oral solution 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.

Taking Morphine Oral Solution with alcohol

You should avoid alcohol whilst taking this medicine.

Pregnancy, breast-feeding and fertility

Pregnancy

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

Continued overleaf

Do not take Morphine oral Solution while you are breastfeeding as morphine sulfate passes into breast milk and will affect your baby. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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

This medicine can affect your ability to drive and operate machinery 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.

This effect is even more enhanced, when used in combination with alcohol or CNS depressants (medicines for sleeping disorders and anxiety). Do not drive or operate machinery if you feel drowsy or cannot think clearly.

Important information about some of the ingredients:

- If you have been told by your doctor that you have an intolerance to some sugars (**sucrose**), contact your doctor before taking this medicinal product
- **sodium propyl hydroxybenzoate (E217)** and **sodium methyl hydroxybenzoate (E219)** may cause an allergic reaction which could be delayed. Although rare, you may have difficulty breathing.
- Morphine Oral Solution contains **alcohol** which may be harmful to those suffering from alcoholism. The amount of alcohol should also be considered if you are pregnant or breast-feeding, have long term (chronic) liver problems or epilepsy, or if you are a child.
- This medicine contains less than 1mmol sodium (23mg) per 1ml. that is to say essentially 'sodium-free'.

3. How to take Morphine Oral Solution

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.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Morphine Oral Solution, 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 using Morphine Oral Solution, in this section).

Your prescriber should have discussed with you, how long the course of Morphine Oral Solution will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Always follow the instructions of your doctor and pharmacist. If you are changing from other types of morphine medication your doctor may

have to change your dose.

This medicine is for oral use

Adults: Recommended dose is one or two 5ml spoonfuls (10-20mg) every 4 hours

Elderly and infirm patients: A reduced dose is recommended

Children: 13 to 18 years: Recommended dose is half or two 5ml spoonfuls (5-20mg) every 4 hours

6 to 12 years: Recommended dose of is half or one 5ml spoonfuls (5-10mg) every 4 hours

1 to 5 years: recommended dose is half a 5ml spoonful (5mg) every 4 hours

Under 1 year: not recommended

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 under active thyroid 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 Morphine Oral Solution 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. Symptoms of an overdose include sudden or unexpected difficulty in breathing, pin-point pupils (the black circle in the centre of your eyes (pupil) getting smaller) or a drop in blood pressure. In the case of infants and children they may suffer fits (convulsions).

People who have taken an overdose may 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.

In more severe cases, very high doses could cause your blood circulation to slow down and cause unconsciousness for a long time, or even death.

If you forget to take Morphine Oral Solution

- If you have missed a dose take it as soon as you remember unless it is nearly time for your next dose. Then continue your normal dose times.
- 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 Morphine Oral Solution

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.

4. Possible Side Effects

Like all medicines, Morphine Oral Solution can cause side effects but not everyone gets them.

Repeated use of morphine can result in tolerance and addiction

Allergic reaction

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, difficult breathing, dizziness and skin reactions such as rash and itching.

- 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).

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)

Other side effects

- Feeling sick (nausea) or being sick (vomiting)
- Constipation, which can be treated with appropriate laxatives
- Difficulty in passing water (urine)
- Feeling drowsy
- Dry mouth, sweating and 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
- Seeing or hearing things that are not there (hallucinations) or feeling confused
- Muscles feeling tense
- The black circle in the centre of your eyes (pupil) getting smaller (miosis)
- An increased sensitivity to pain
- Unknown frequency - Dependence and addiction (see section "How do I know if I am addicted?")
- 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.

Drug Withdrawal

When you stop taking Morphine Oral Solution, 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 Morphine Oral Solution, 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

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 at: 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 Morphine Oral Solution

Keep this medicine out of the sight and reach of children. Do not use this product after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Keep container in the outer carton. Use within 90 days of first opening.

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

Please return any remaining medicine to your pharmacist 90 days after first opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other Information

What Morphine Oral Solution contains:

Active ingredient: Morphine Sulfate Ph Eur 10mg in each 5ml of solution.

Other ingredients: sugar (sucrose), alcohol, disodium edetate, sodium propyl hydroxybenzoate (E217), sodium methyl hydroxybenzoate (E219), raspberry flavour, purified water and may include hydrochloric acid.

Each 5ml dose of this solution contains 0.4ml of alcohol and 2.25g of sugar.

What Morphine Oral Solution looks like and contents of the pack:

The clear, colourless or almost colourless solution is supplied in amber glass bottles containing 100ml, 250ml, 300ml or 500ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Martindale Pharmaceuticals Ltd
Bampton Road, Romford,
Essex, RM3 8UG, UK

Product Licence No.: PL 00156/0036

This leaflet was last revised in: December 2023

M MARTINDALE PHARMA
Bampton Road, Harold Hill, Romford, RM3 8UG, UK

The following information is intended for healthcare professionals only:

Physicochemical incompatibility (formation of precipitates) has been demonstrated between solutions of morphine sulphate and 5- fluorouracil

D0614200000



DEVELOPMENT ARTWORK

Component Code: D06142

Prod: Morphine Sulfate 10mg/5ml PIL
UK Oral Solution

Paper Size: 340 x 260mm

Version Control	Date	By
Version A:	12/12/23	LB
Version B:		
Version C:		
Version D:		
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		

me&you
The Old Printworks, High Street, Otford,
Sevenoaks, Kent. TN14 5PQ
t: +44 (0) 1732 743 455
e: pharma@meandyou.co.uk
www.meandyou.co.uk