Package leaflet: Information for the user

***Morphine Sulfate Mundipharma* 10 mg, 30 mg and 60 mg prolonged release tablets**
Morphine sulfate

<u>This medicine contains morphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.</u>

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.

In this leaflet:
1. What ***Morphine Sulfate Mundipharma*** tablets are and what they are used for
2. What you need to know before you take ***Morphine Sulfate Mundipharma*** tablets
3. How to take ***Morphine Sulfate Mundipharma*** tablets
4. Possible side effects
5. How to store ***Morphine Sulfate Mundipharma*** tablets
6. Contents of the pack and other Information

1. What *Morphine Sulfate Mundipharma* tablets are and what they are used for
This medicine has been prescribed for you for the relief of severe pain over a period of 12 hours. It contains morphine, which belongs to a class of medicines called opioids, which are 'pain relievers'.

The medicine has been prescribed for 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 doctor 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 *Morphine Sulfate Mundipharma* tablets

Do not take *Morphine Sulfate Mundipharma* tablets if:
- you are allergic to morphine or any of the other ingredients of this medicine (listed in section 6);
- you have breathing problems, such as obstructive airways disease, respiratory depression, or severe asthma. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- you have a condition where the small bowel (part of your gut) does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen;
- you have a head injury that causes a severe headache or makes you feel sick. This is because the tablets may make these symptoms worse or hide the extent of the head injury;
- you have recent onset liver disease;
- you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;

- the patient is under one year of age.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital that you are taking these tablets. Your doctor may adjust your treatment. These tablets should not be used for short-term pain after an operation owing to the increased risk of dependence and breathlessness.

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 Sulfate Mundipharma*** tablets 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 Sulfate Mundipharma*** tablets 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 Sulfate Mundipharma*** tablets, 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 Sulfate Mundipharma*** tablets).

Warnings and precautions
Talk to your doctor or pharmacist before taking these tablets if you:
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating when you have stopped taking alcohol or drugs;
- feel you need to take more ***Morphine Sulfate Mundipharma*** tablets 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 doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever;
- have breathing problems, such as impaired lung function or severe bronchial asthma. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness and coughing;

- have a severe heart problem after long-term lung disease (severe cor pulmonale);
- have a head injury, severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- have low blood pressure;
- have an under-active thyroid gland (hypothyroidism);
- have severe kidney or liver problems;
- suffer from, or have ever suffered from epilepsy, seizures, fits or convulsions;
- have inflammation of the pancreas or have problems with your gall bladder due to gall stones;
- have an inflammatory bowel disorder;
- you suffer from constipation;
- have prostate problems;
- experience weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenal glands producing too little of the hormone 'cortisol', and you may need to take a hormone supplement;
- have loss of libido, impotence or your menstrual cycle stops. This may be because of decreased sex hormone production;
- have sickle cell disease.

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.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be using 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 doctor 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 doctor 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.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with ***Morphine Sulfate Mundipharma*** tablets 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 Sulfate Mundipharma*** tablets or other opioids. Stop using ***Morphine Sulfate Mundipharma*** tablets and seek medical attention immediately, if you notice any of the following symptoms: blistering, widespread scaly skin or pus-filled spots together with fever.

<u>Sleep-related breathing disorders</u>
Morphine Sulfate Mundipharma tablets can cause breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in 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 observes these symptoms contact your doctor. A dose reduction may be considered by your doctor.

You may experience hormonal changes while taking these tablets. Your doctor may want to monitor these changes.

Other medicines and *Morphine Sulfate Mundipharma* tablets
Concomitant use of ***Morphine Sulfate Mundipharma*** tablets 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 Sulfate Mundipharma*** tablets together with sedative medicines, the dosage 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 dosage 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.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you take these tablets with some other medicines, the effect of the tablets or the other medicine may be changed.

Morphine Sulfate Mundipharma tablets must not be used together with a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks (see Section 2 'Do not take')

Tell your doctor or pharmacist if you are taking any of the medicines mentioned below. A large number of drugs can interact with morphine sulfate tablets which can significantly alter their effects. These drugs include:

- medicines to help you sleep (for example benzodiazepines, tranquillisers, hypnotics or sedatives);
- medicines to treat psychiatric or mental disorders (such as phenothiazines);
- muscle relaxants;
- medicines to treat high blood pressure;
- cimetidine to treat stomach ulcers, indigestion or heartburn;
- certain types of medicines to stop you feeling or being sick;
- medicines used to prevent or relieve the symptoms of an allergy (antihistamines);
- rifampicin to treat tuberculosis;
- ritonavir to treat HIV;
- medicines to treat Parkinson's disease;
- 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 morphine.

Also tell your doctor if you have recently been given an anaesthetic.

***Morphine Sulfate Mundipharma* tablets and alcohol**
Drinking alcohol whilst taking ***Morphine Sulfate Mundipharma*** tablets may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping

breathing, and loss of consciousness. It is recommended not to drink alcohol while you are taking ***Morphine Sulfate Mundipharma*** tablets.

Pregnancy and breastfeeding
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.

Do not take ***Morphine Sulfate Mundipharma*** tablets if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby. If you take ***Morphine Sulfate Mundipharma*** tablets during pregnancy your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated, such as high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating.

Do not take ***Morphine Sulfate Mundipharma*** tablets while you are breastfeeding as morphine passes into breast milk and will affect your baby.

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

- 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 and 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.

Morphine Sulfate Mundipharma **tablets contain lactose and sunset yellow (E110)**
The 10 mg, 30 mg and 60 mg tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

The 30 mg and 60 mg tablets contain sunset yellow (E110) which may cause allergic reactions.

3. How to take *Morphine Sulfate Mundipharma* tablets
Always take the tablets exactly as your doctor has told you. The label on your medicine will tell you how many tablets to take and how often. 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 ***Morphine Sulfate Mundipharma*** tablets, 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 **Morphine Sulfate Mundipharma** tablets, in this section). They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Swallow your tablets whole with a glass of water**. Do not break, crush or chew the tablets.**

Morphine Sulfate Mundipharma **tablets are designed to work properly over 12 hours when swallowed whole. If a tablet is broken, crushed or chewed, the entire 12-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.**

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

You should take your tablets every 12 hours. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock in the evening.

Adults
The usual starting dose is one 30 mg tablet every 12 hours. However, the dose will depend on your age, weight and the severity of your pain. If you are elderly or weigh less than 70 kg your doctor may suggest a lower starting dose. Your doctor will decide how many tablets you should take.

Children over one year of age
Children over one year of age can take the tablets. The required dose will depend on their weight and severity of pain. This should be discussed with your doctor or pharmacist.

If you find that you are still in pain whilst taking these tablets discuss this with your doctor.

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

If you take more *Morphine Sulfate Mundipharma* tablets than you should or if someone accidentally swallows your tablets
Call your doctor or hospital straight away as you may need emergency treatment. People who have taken an overdose may feel very sleepy, sick, dizzy 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.

An overdose may result in:
- A brain disorder (known as toxic leukoencephalopathy)

When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show to the doctor.

If you forget to take *Morphine Sulfate Mundipharma* tablets
If you remember within 4 hours of the time your tablet was due, take your tablet straight away. Take your next tablet at your normal time. If you are more than 4 hours late, please call your doctor for advice. Do not take a double dose to make up for a forgotten tablet.

If you stop taking *Morphine Sulfate Mundipharma* tablets
Do not suddenly stop taking this medicine. If you want to stop taking this medicine discuss this with your doctor 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, these tablets can cause side effects, although not everybody gets them.

Stop using ***Morphine Sulfate Mundipharma*** tablets and **seek medical attention immediately** if you notice any of the following symptoms:

- Sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. These may be signs of a severe allergic reaction.
- 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).
- You begin to breathe more slowly or weakly than expected. This could be a sign of a condition called respiratory depression.

The following side effects may also occur:

Very common side effects (may affect more than 1 in 10 people)

- Constipation (your doctor can prescribe a laxative to overcome this problem).
- Feeling sick.

Common side effects (may affect up to 1 in 10 people)

- Drowsiness (this is most likely when you first start taking your tablets or when your dose is increased, but it should wear off after a few days).
- Dry mouth, loss of appetite, abdominal pain or discomfort.
- Vomiting (being sick). This should normally wear off after a few days. However, your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.
- Dizziness, headache, confusion, difficulty in sleeping.
- A feeling of unusual weakness.
- Generally feeling unwell, tiredness.
- Involuntary muscle contractions.
- Rash or itchy skin.
- Sweating.

Uncommon side effects (may affect up to 1 in 100 people)

- Withdrawal symptoms (see section ‘Drug Withdrawal’).
- Difficulty in breathing (possibly due to fluid on the lungs) or wheezing.
- A condition where the bowel does not work properly (ileus).
- Changes in taste, indigestion.
- A feeling of dizziness or ‘spinning’, fainting, seizures, fits or convulsions.
- Agitation, mood changes, hallucinations, a feeling of extreme happiness.
- Unusual muscle stiffness.
- Tingling or numbness.
- Difficulty in passing urine.
- Low blood pressure, facial flushing (redness of the face).
- Palpitations.
- Swelling of the hands, ankles or feet.
- Hives.

- A worsening in liver function tests (seen in blood test).
- Blurred vision.
- Muscle spasms.

Frequency not known (frequency cannot be estimated from the available data)
- Sleep apnoea (breathing pauses during sleep).
- Dependence and addiction (see section 'How do I know if I am addicted?').
- Unpleasant or uncomfortable mood, abnormal thoughts.
- An increased sensitivity to pain.
- Reduction in size of the pupils in the eye.
- A fast or slow heartbeat.
- High blood pressure.
- Decreased cough reflex.
- 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.
- Severe pain in the lower abdomen or bladder that may come and go.
- Impotence, decreased sexual drive, absence of menstrual periods.
- Withdrawal symptoms in babies born to mothers who have used ***Morphine Sulfate Mundipharma*** tablets in pregnancy (See section 2 'Pregnancy, breastfeeding and fertility').

<u>Drug withdrawal</u>
When you stop taking ***Morphine Sulfate Mundipharma*** tablets 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 Sulfate Mundipharma*** tablets 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 doctor.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Sulfate Mundipharma* 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.

Do not store your tablets above 25°C.

Do not take your tablets if they are broken or crushed as this can be dangerous and can cause serious problems such as overdose.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What *Morphine Sulfate Mundipharma* tablets contain
The active ingredient is morphine sulfate. Each tablet contains 10 mg, 30 mg or 60 mg of morphine sulfate.

The other ingredients are:
- Hydroxyethylcellulose
- Cetostearyl alcohol
- Magnesium stearate
- Talc
- Lactose (except for 100 mg and 200 mg tablets)
- Hypromellose (E464) (except for 10 mg)
- Macrogol
- Titanium dioxide (E171)
- Polyvinyl alcohol (10 mg only)

The tablets also contain the following colourants:
10 mg – Iron oxide (E172)
30 mg – Erythrosine (E127), indigo carmine (E132) and sunset yellow (E110)
60 mg – Erythrosine (E127), quinoline yellow (E104) and sunset yellow (E110)

What *Morphine Sulfate Mundipharma* tablets look like and the contents of the pack
The tablets are marked with NAPP on one side and the strength (e.g. 10 mg etc) on the other. The tablets are coloured as follows: 10 mg – golden brown, 30 mg –purple, 60 mg – orange.

In each box there are 60 tablets.

Marketing Authorisation Holder
Mundipharma Corporation (Ireland) Limited, United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Manufacturer
Bard Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line (free of charge) on: 0800 198 5000
You will need to give details of the product name and reference number. These are as follows:
Product name: ***Morphine Sulfate Mundipharma*** tablets
Reference number: 59242/0018

This leaflet was last revised in July 2025.