Package leaflet: Information for the user

Morphgesic® SR 10 mg, 30 mg, 60 mg and 100 mg Tablets
morphine hemisulfate 2.5-hydrate

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.

This medicine contains morphine hemisulfate 2.5-hydrate which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

What is in this leaflet
1. What Morphgesic SR Tablets are and what they are used for
2. What you need to know before you take Morphgesic SR Tablets
3. How to take Morphgesic SR Tablets
4. Possible side effects
5. How to store Morphgesic SR Tablets
6. Contents of the pack and other information

1. What Morphgesic SR Tablets are and what they are used for

This medicine has been prescribed for you for prolonged relief from severe pain for up to 12 hours. It contains morphine hemisulfate 2.5-hydrate, 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 Morphgesic SR Tablets

Do not take Morphgesic SR Tablets
- if you are **allergic** to morphine hemisulfate 2.5-hydrate or any of the other ingredients of this medicine (listed in section 6). Allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing;
- if you have any long standing **lung disease** (such as obstructive airways disease or bronchitis) or problems with your breathing;
- if you are having an **asthma attack;**
- if you have a problem with excessive phlegm;
- if you have recently suffered any **head injury** or have been told that you have raised pressure around your brain;
- if you have **liver disease;**
- if you have an inflammatory bowel disease such as ulcerative colitis;
- if you have any problems with your stomach or bowel (where your bowel or stomach function has slowed down or stopped working) or you have severe pain in your abdomen;

- if you often drink large amounts of **alcohol;**
- if you are taking, or have recently taken (within the last 14 days) a medicine from a group of anti-depressants called monoamine oxidase inhibitors (MAOIs) see section ‘Other medicines and Morphgesic SR Tablets';
- if you have heart failure caused by long term lung disease;
- if you have severely impaired kidney or liver function;
- if you are about to have an operation, or recently had an operation;
- if you are pregnant or think you may be pregnant or if you are breast-feeding.

Warnings and precautions

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 Morphgesic SR 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 Morphgesic SR 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 Morphgesic SR 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 Morphgesic SR Tablets).

Talk to your doctor or pharmacist before taking Morphgesic SR Tablets:

- if you have breathing problems such as impaired lung function;
- if you have any problems with your thyroid or adrenal glands;
- if you have impaired liver or kidney function;
- if you are a man with an enlarged prostate gland;
- if you have any problems urinating;
- if you have epilepsy or suffer from fits (seizures);
- if you are suffering with shock;
- if you are suffering from myasthenia gravis (a disease which affects the muscles);
- if you have bowel problems e.g. inflammatory or obstructive bowel disorder;

- if you have low blood pressure and a decreased volume of blood circulating (hypovolaemia);
- if you have a severe heart problem after long-term lung disease (severe cor pulmonale);
- if you suffer with a disease of your bile duct;
- if you have pancreatitis (inflammation and swelling of the pancreas);
- if you have a rare form of tumour affecting part of the body known as the adrenal glands (phaeochromocytoma);
- if you are elderly.
- if you are taking any medicine from the group of medicines known as benzodiazepines. Taking these medicines with Morphgesic SR Tablets may result in sedation, difficulties in breathing (respiratory depression), coma and may be fatal. Even if benzodiazepines are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.
- if you experience weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take hormone supplement.
- if you experience loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production.
- 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 feel you need to take more of Morphine Hemisulfate 2.5-hydrate Injection 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.

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

Sleep-related breathing disorders
Morphgesic SR Tablets 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.

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.

If any of these apply to you, or if you are not sure, tell your doctor before taking Morphgesic SR Tablets.

Children
Morphgesic SR Tablets are not recommended for children.

Other medicines and Morphgesic SR Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
Morphgesic SR 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 'Do not take...'). Examples include tranylcypromide, phenelzine, isocarboxazid, moclobemide and linezolid.

This is especially important if you are taking any of the medicines mentioned below or medicines for:
- depression (e.g. amitriptyline, imipramine or dosulepin);
- psychoses (e.g. chlorpromazine, promazine);
- sedative or hypnotic purposes (e.g. zopiclone, zolpidem);
- gabapentin or pregabalin to treat epilepsy or neuropathic pain (pain due to nerve problems);
- other opioid analgesics such as buprenorphine, nalbuphine or pentazocine;
- anaesthesia (e.g. thiopental, isoflurane);
- palpitations (e.g. mexiletine or propranolol or esmolol);
- nausea and vomiting (e.g. metoclopramide, domperidone);
- ulcer healing (e.g. cimetidine, ranitidine);
- anti-histamine drugs;
- medicines to treat Parkinson's disease;
- rifampicin to treat e.g. tuberculosis;
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine.
- ritonavir to treat HIV;
- dexamfetamine to treat narcolepsy or attention-deficit hyperactivity disorder (ADHD);
- diuretic drugs to cause increase urine production.
- other analgesics (e.g. **Buprenorphine, nalbuphine, pentazocine**).

Morphine may increase the effects of medicines used to control high blood pressure, relax muscles or act as tranquilisers.

Concomitant use of Morphgesic SR 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 Morphgesic SR Tablets 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.

Morphgesic SR Tablets with food, drink and alcohol
Do not drink alcohol while taking Morphgesic SR Tablets, as the tablets can increase the effects of alcohol.

Pregnancy and breast-feeding

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.

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

Breast-feeding
Do not take Morphgesic SR Tablets while you are breastfeeding as morphine hemisulfate 2.5-hydrate passes into breast milk and will affect your baby.

Driving and using machines
Morphgesic SR 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). If you are affected you should not drive or use machinery.

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.

Morphgesic SR Tablets contains colourant E110 and lactose
- The colourant E110 is present in the 30 mg and 60 mg tablets. This may cause allergic reactions.

- If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicinal product**.** This is because Morphgesic

SR Tablets (except 100 mg tablets) contains a small amount of **lactose**, a type of sugar.

3. How to take Morphgesic SR Tablets

Your prescriber should have discussed with you, how long the course of tablets 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 take this medicine exactly as your doctor or pharmacist 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 Morphgesic SR 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 Morphgesic SR Tablets, in this section).

The recommended starting dose is one or two 10 mg tablets twice daily. The total daily dose should be taken in two divided doses at 12 hourly intervals. 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.

Swallow your tablets whole with water. **Do not** crush or chew them.

Your doctor may change your dose depending on your response and how severe your pain is.

Do not take more tablets than the doctor has told you.

If you take more Morphgesic SR Tablets than you should
Please be aware of the symptoms you may experience from taking too much of your Morphgesic SR medicine. These include extreme drowsiness, pinpoint pupils, confusion, cold and clammy skin, a weak pulse, slowed heart beat, shallow breathing, floppiness or fainting. 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.

If you have taken too many Morphgesic SR Tablets, contact your doctor or nearest hospital emergency department **immediately.** Take the container and any remaining tablets with you.

If you forget to take Morphgesic SR Tablets:
If you forget to take a dose, just take the next dose at the usual time, Do not take a double dose to make up for a forgotten tablet.

If you stop taking Morphgesic SR Tablets

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.

Serious allergic reaction which causes difficulty in breathing or dizziness. All medicines can cause allergic reactions, although serious allergic reactions are uncommon. Tell your doctor immediately if you experience sudden wheeziness, difficulties in breathing or dizziness, swelling of the eyelids, face or lips, rash or itching, especially those covering your whole body.

Morphgesic SR Tablets use may result in coma

Stop using Morphgesic SR Tablets and seek medical attention immediately if you notice any of the following symptoms:
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).

Sometimes Morphgesic SR Tablets can aggravate “spasm” (or contraction) of the bile duct (which is attached to the gall bladder) or ureter (which drains urine from the kidneys to the bladder).
These effects can lead to abdominal pain or difficulty in passing water.

If you notice:
- swelling of your stomach,
- pain and discomfort,
- being sick,
- constipation;
  stop taking this medicine and seek medical advice immediately. These may be signs of a condition called Paralytic Ileus (paralysis of the bowel).

Other side effects of Morphgesic SR Tablets may include:

Very common: may affect more than 1 in 10 people

• feeling sick (nausea);
• constipation;

Common: may affect up to 1 in 10 people
• headache;
• abdominal or stomach pain;
• anorexia;
• unusual body movements, particularly of the hands, arms or legs;
• itching;
• insomnia;
• dizziness;
• sweating;
• a feeling of unusual weakness;
• being sick;
• drowsiness;

• confusion.

Uncommon: may affect up to 1 in 100 people
• allergic reaction;
• nettle rash;
• facial flushing (red face);
• fainting;
• feeling of an imbalance (vertigo);
• low blood pressure;
• swelling (oedema);
• feeling your heartbeat (palpitations);
• urinary retention or painful urination;
• vision abnormalities;
• changes in taste;
• fits;
• muscle twitches, spasms, tremors or injury;
• increased liver enzymes;
• breathing difficulties such as wheezing or increased fluid on the lungs;
• an elevated sense of well-being (euphoria);
• agitation;
• disorientation or mood changes;
• seeing or hearing things that are not really there (hallucinations);
• experiencing 'pins and needles';

Not Known: frequency cannot be estimated from the available data
• dry mouth;
• dependence and addiction (see section "How do I know if I am addicted?");
• high blood pressure, or circulatory failure;
• raised intracranial pressure (severe headache, feeling sick);
• decreased heart rate;
• slow or irregular heart beat;
• increased heart rate;
• reduction in the male hormone, testosterone. This may cause small testicles and loss of body hair, if morphine is used for a long period of time in men;
• changes in blood counts which may cause unexpected bruising and bleeding;
constriction of the pupils (small pupils);
• loss of periods or decreased sex drive;
• erectile dysfunction;
• disruption of menstruation;
• paralysis of gut (narcotic bowel syndrome);
• increased sensitivity to pain and touch (hyperaesthesia/allodynia);
• tolerance (progressively increased doses may be required in order to have a sufficient therapeutic effect)
• exacerbation of pancreatitis (this can cause severe pain in the abdomen and back, nausea, vomiting, constipation and dry mouth);
• cough decreased
• thinking disturbances;
• restlessness
• light-headedness
• generally feeling unwell.
• 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.

Some of these effects are more common if you are mobile than if you are confined to bed.

Drug Withdrawal
When you stop taking morphine hemisulfate 2.5-hydrate, 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 Morphgesic SR 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 prescriber

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 Website: 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 Morphgesic SR Tablets

Keep this medicine out of the sight and reach of children.
Do not store above 25ºC. Store in the original package.
Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

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 Morphgesic SR Tablets contains
There are 4 different strengths (10 mg, 30 mg, 60 mg and 100 mg) of Morphgesic SR Tablets.
The active substance is morphine hemisulfate 2.5-hydrate.
The other ingredients are lactose (except 100 mg tablets), povidone, hydroxyethylcellulose, talc, magnesium stearate, hypromellose (E464), macrogol and industrial methylated spirit 99%.

The different strength tablets also contain the following colourants:

10 mg tablets: Titanium Dioxide (E171), Iron Oxide Yellow (E172) and Iron Oxide Red (E172).
30 mg tablets: Titanium Dioxide (E171), Erythrosine (E127), Indigo Carmine (E132) and Sunset Yellow (E110).
60 mg tablets: Titanium Dioxide (E171) and Sunset Yellow (E110).
100 mg tablets: Titanium Dioxide (E171) and Iron Oxide Black (E172).

What Morphgesic SR Tablets look like and contents of the pack
10 mg tablets are buff, embossed with 10 on one face and contain 10 mg of the active ingredient morphine hemisulfate 2.5-hydrate.
30 mg tablets are violet, embossed with 30 on one face and contain 30 mg of the active ingredient morphine hemisulfate 2.5-hydrate.
60 mg tablets are orange, embossed with 60 on one face and contain 60 mg of the active ingredient morphine hemisulfate 2.5-hydrate.
100 mg tablets are grey, embossed with 100 on one face and contain 100 mg of the active ingredient morphine hemisulfate 2.5-hydrate.

Each strength of Morphgesic SR Tablets is available in packs containing 10 or 60 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder:
Amdipharm UK Limited,
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS, United Kingdom

Manufacturer:
Aesica Queenborough Limited,
North Road,
Queenborough,
Kent,
ME11 5EL,
United Kingdom.

This leaflet was last revised in June 2026.
® *Amdipharm is licensed to use the registered trademark.*