

Package leaflet: Information for the user

***MST® Continus®* 5 mg, 10 mg, 15 mg, 30 mg and 100 mg prolonged-release tablets**
Morphine sulfate

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.

What is in this leaflet:

1. What *MST Continus* tablets are and what they are used for
2. What you need to know before you take *MST Continus* tablets
3. How to take *MST Continus* tablets
4. Possible side effects
5. How to store *MST Continus* tablets
6. Contents of the pack and other information

1. What *MST Continus* tablets are and what they are used for

These tablets have been prescribed for you by your doctor to relieve severe pain over a period of 12 hours. They contain the active ingredient morphine which belongs to a group of medicines called strong analgesics or 'painkillers'.

***MST Continus* tablets are designed to work properly over 12 hours when swallowed whole. If a tablet is broken, crushed, dissolved 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.**

2. What you need to know before you take *MST Continus* tablets

Do not take *MST Continus* tablets if:

- you are allergic (hypersensitive) to morphine or any of the other ingredients of *MST Continus* tablets (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 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 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 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, please tell the doctor at the hospital that you are taking these tablets.

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 **MST Continus** 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 **MST Continus** 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 **MST Continus** 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 **MST Continus** tablets).

Warnings and precautions

Talk to your doctor or pharmacist before taking **MST Continus** tablets if you:

- have breathing problems, such as severe bronchial asthma or impaired lung function. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- have an under-active thyroid gland (hypothyroidism), kidney or long-term liver problems as you may need a lower dose;
- have a severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- suffer from or have ever suffered from epilepsy, seizures, fits or convulsions;
- have low blood pressure;
- have a severe heart problem after long-term lung disease (severe cor pulmonale);
- have inflammation of the pancreas (which causes severe pain in the abdomen and back) or problems with your gall bladder;
- have an inflammatory bowel disorder;
- you suffer from constipation;
- have prostate problems;
- have increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or a change in strong analgesic (“painkiller”), (see section 2);
- 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, cessation of menstruation. This may be because of decreased sex hormone production;

- have previously been dependent on drugs or alcohol. Also tell your doctor if you feel that you are becoming dependent on this medicine while you are using it. You may have started to think a lot about when you can take the next dose, even if you do not need it for the pain;
- have withdrawal (abstinence) symptoms or dependence. The most common abstinence symptoms are mentioned in section 3. If this occurs, your doctor may change the type of medicine or the times between doses.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with ***MST Continus*** 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 ***MST Continus*** tablets or other opioids. Stop using ***MST Continus*** 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

MST Continus tablets can cause breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in blood) or worsen already existing problems while sleeping. 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.

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 *MST Continus* tablets

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

Concomitant use of ***MST Continus*** 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 ***MST Continus*** 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 recommendations closely. It could be helpful to inform friends and relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

MST Continus tablets must not be used together with a type of medicine known as 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 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.

***MST Continus* tablets with alcohol**

Drinking alcohol whilst taking ***MST Continus*** 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 ***MST Continus*** tablets.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Prolonged use of morphine during pregnancy may cause withdrawal symptoms in newborns, which should be treated by a doctor. Withdrawal (abstinence) symptoms in babies born to mothers who have used ***MST Continus*** tablets in pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating.

Driving and using machines

MST Continus 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 ***MST Continus*** tablets, or when changing to a higher dose. If you are affected, you should not drive or use machinery.

***MST Continus* tablets contain lactose and Sunset Yellow (E110)**

The 5 mg, 10 mg, 15 mg and 30 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 tablets contain Sunset yellow (E110) which may cause allergic reactions.

3. How to take *MST Continus* tablets

Always take ***MST Continus*** 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 ***MST Continus*** 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 ***MST Continus*** tablets, in this section).

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

***MST Continus* 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 for adults 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.

Use in children over one year of age

Children over one year of age can take *MST Continus* 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 *MST Continus* 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 *MST Continus* tablets than you should

Call your doctor or hospital straight away as you may need emergency treatment in hospital. People who have taken an overdose may feel very sleepy, sick, dizzy, get a brain disorder (known as toxic leukoencephalopathy) 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. 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 *MST Continus* 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 *MST Continus* tablets

Do not stop treatment with these tablets unless agreed with your doctor. If you want to stop the treatment with these tablets, ask your doctor how to slowly decrease the dose so you avoid abstinence symptoms. Abstinence (withdrawal) symptoms may include body aches, tremors, diarrhoea, stomach pain, nausea, flu-like symptoms, fast heartbeat and large pupils. Psychological symptoms include an intense feeling of unsatisfaction, anxiety and irritability.

If you have any further questions on the use of *MST Continus* tablets, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, *MST Continus* tablets can cause side effects, although not everybody gets them. Stop using *MST Continus* tablets and seek medical attention immediately if you notice any of the following symptoms:

- All medicines can cause allergic reactions, although serious allergic reactions are uncommon. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.
- 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).
- The most serious side effect, although uncommon, is a condition where you breathe more slowly or weakly than expected (respiratory depression).

As with all strong painkillers, there is a risk that you may become addicted or reliant on ***MST Continus*** tablets.

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 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).
- Headache, dizziness, 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)

- 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 a blood test).
- Blurred vision.
- Muscle spasms.

Frequency unknown (cannot be estimated from the available data)

- Sleep apnoea (breathing pauses during sleep)
- Unpleasant or uncomfortable mood, abnormal thoughts.
- An increased sensitivity to pain.
- Reduction in size of the pupils in the eye.
- A fast or slow heart beat.
- 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.
- Impotence, decreased sexual drive, absence of menstrual periods.
- Withdrawal symptoms (such as agitation, anxiety, shaking or sweating upon stopping taking ***MST Continus*** tablets) or dependence.
- Withdrawal symptoms in babies born to mothers who have used ***MST Continus*** tablets in pregnancy (See section 2 “Pregnancy, breastfeeding and fertility”).

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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *MST Continus* tablets

Keep out of the sight and reach of children.

Do not use any tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C. Store in the original package.

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 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 *MST Continus* tablets contain

The active ingredient is morphine sulfate. Each tablet contains 5 mg, 10 mg, 15 mg, 30 mg or 100 mg of morphine sulfate.

The other ingredients are:

- Hyetellose
- Cetostearyl alcohol
- Magnesium stearate
- Talc
- Lactose (except for 100 mg)
- 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)

15 mg - Iron oxide (E172), brilliant blue (E133), quinoline yellow (E104) and indigo carmine (E132)

30 mg – Erythrosine (E127), indigo carmine (E132) and sunset yellow (E110)

100 mg - Iron oxide (E172) and indigo carmine (E132)

What *MST Continus* tablets look like and the contents of the pack

MST Continus tablets are marked with NAPP on one side and the strength (e.g. 5 mg, 10 mg, etc) on the other.

The tablets are film-coated in the following colours: 5 mg - white, 10 mg – golden brown, 15 mg - green, 30 mg – purple, 100 mg – grey.

In each box there are 60 tablets.

Marketing Authorisation Holder

Mundipharma Pharmaceuticals Limited, United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Manufacturer

Mundipharma DC B.V., Leusderend 16, 3832 RC Leusden, Netherlands.

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 on:

0044 1733 37 53 70

You will need to give details of the product name and reference number.
These are as follows:

Product name: MST Continus prolonged release tablets

Reference number: 1688/4/1

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