



## Package leaflet: Information for the user

### ***MST® Continus® 5 mg, 10 mg, 15 mg, 30 mg, 60 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 or respiratory depression. 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 tranlylcypromine, 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.

#### **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;
- have prostate problems;
- have poor adrenal gland function (your adrenal gland is not working properly which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick);
- are or have ever been addicted to alcohol or drugs;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, upon stopping taking alcohol or drugs;

- have an increased sensitivity to pain despite the fact that you are taking increasing doses of the tablets (hyperalgesia). Your doctor will decide whether you need a change in dose or a change in strong analgesic (“painkiller”).

#### **Other medicines and *MST Continus* tablets**

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 these tablets or the other medicine may be changed.

*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:

- 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 to treat epilepsy or neuropathic pain (pain due to nerve problems).

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. Withdrawal 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, 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 *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.

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 or get pneumonia from inhaling vomit or foreign matter (symptoms may include breathlessness, cough and fever). They 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

You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects.

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.

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.

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)

- 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.
- Colicky abdominal pain or discomfort, an increase in the severity of symptoms associated with inflammation of the pancreas.
- Impotence, decreased sexual drive, absence of menstrual periods.
- Withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking **MST Continus** tablets.
- 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@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, 60 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)  
60 mg - Erythrosine (E127), quinoline yellow (E104) 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, 60 mg - orange, 100 mg – grey.

In each box there are 60 tablets.

##### Marketing Authorisation Holder

Mundipharma Pharmaceuticals Limited, Millbank House, Arkle Road, Sandyford, Dublin 18, 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 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

**This leaflet was last revised in January 2017.**

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