

MST CONTINUS[®] TABLETS

Morphine sulphate (10mg, 30mg)

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What MST Continus[®] is used for

These tablets have been prescribed for you by your doctor to relieve severe pain over a period of 12 hours.

How MST Continus[®] works

They contain the active ingredient morphine which belongs to a group of medicines called strong analgesics or 'painkillers'

Before you take MST Continus[®]

-When you must not use it

Do not take MST Continus[®] tablets if you:

- are allergic (hypersensitive) to morphine or any of the other ingredients of the tablets (see section 7 'Product Description');
- have breathing problems, such as obstructive airways disease or respiratory depression. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- 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;
- 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 are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranlylcpromide, 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.

-Before you start take it

Before treatment with these tablets tell your doctor or pharmacist if you:

- have breathing problems, such as impaired lung function or severe bronchial asthma. Symptoms may include breathlessness and coughing;
- have an under-active thyroid gland (hypothyroidism), severe kidney or 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 an 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 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 these tablets (hyperalgesia). Your doctor will decide whether you need a change in dose or a change in strong analgesic ("painkiller").

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including

medicines obtained without a prescription. If you take these tablets with some other medicines, the effect of the tablets or the other medicine may be changed.

These tablets must not be used together with a monoamine oxidase inhibitor or you have taken this type of medicine in the last two weeks. Taking MST Continus[®] with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepines.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Tell your doctor or pharmacist if you are taking:

- medicines to help you sleep e.g. tranquillisers, hypnotics or sedatives;
- medicines to treat psychiatric or mental disorders e.g. 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,

How to use MST Continus[®]

-How much to use

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. Swallow your tablets whole with a glass of water. Do not break, 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 take MST Continus® tablets by mouth. The tablets should never be crushed or injected as this may lead to serious side effects, which may be fatal.

Adults and elderly patients

The usual starting dose is one 30 mg MST Continus® tablet for 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

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.

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

-When to use it

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.

-How long to use it

Continue taking your medicine for as long as your doctor tells you.

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.

Withdrawal symptoms such as agitation, anxiety, shaking or sweating may occur if you suddenly stop taking these tablets

- If you forget to use it

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 use too much (overdose)

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). 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.

While you are taking it

-Things you must do

Take MST Continus® tablets exactly as your doctor has prescribed. Before you start on a new medicine, remind your doctor and pharmacist that you are taking MST Continus® tablets. Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery. If you become pregnant while taking this medicine, tell your doctor immediately. Keep all of your doctor's appointments so that your progress can be checked. Tell your doctor if your pain is getting worse or you are having more frequent breakthrough pain. Also tell your doctor if you are having any problems or difficulties while you are being treated with MST Continus® tablets. Tolerance to morphine may develop which means that the effect of the medicine may decrease. If this happens, your doctor may increase the dose so that you get adequate pain relief. Keep enough MST Continus® tablets with you to last over weekends and holidays

-Things you must not do

Do not take MST Continus® tablets to treat any other complaint unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you. Do not stop taking your medicine, exceed the dose recommended or change the dosage without checking with

your doctor. Over time your body may become used to you taking morphine so if you stop taking it suddenly, your pain may worsen and you may have unwanted side effects such as withdrawal symptoms such as agitation, anxiety, palpitations, shaking or sweating. This is called physical dependence. If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

Taking 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.

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 5 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.

Pregnancy and breastfeeding

Do not take these tablets if you are pregnant or breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist

- Things to be careful of

Do not drive or operate machinery until you know how MST Continus® tablets affect you. MST Continus® tablets may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness. Discuss these aspects and any impact on your driving or operating machinery with your doctor. Be careful if you are elderly, unwell or taking other medicines. Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall. If you feel light-headed, dizzy or faint when getting out of

bed or standing up, get up slowly. Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor. Tell your doctor if you suffer from nausea or vomiting when taking MST Continus® tablets. If you vomit after your dose, your pain may come back, as you may not have absorbed your medicine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help you stop vomiting. Tell your doctor if taking MST Continus® tablets causes constipation. Your doctor can advise you about your diet, the proper use of laxatives and suitable exercise you can do to help you manage this. There is potential for abuse of morphine and the development of addiction to morphine. It is important that you discuss this issue with your doctor.

Serotonin syndrome: MST Continus® may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

Adrenal insufficiency: Long-term use of MST Continus® may cause adrenal insufficiency, a potential life-threatening condition that may be present with a non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

Infertility: Long-term use of MST Continus® may cause reduced fertility. It is not known whether these effects on fertility are reversible

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

Frequency not known

(Frequency cannot be estimated from the available data)

- Unpleasant or uncomfortable mood, abnormal thoughts.
- An increased sensitivity to pain.
- Sleep apnoea
- Reduction in size of the pupils in the eye.
- A fast or slow heartbeat.
- High blood pressure.
- Decreased cough reflex.
- Colicky abdominal pain or discomfort, an increase in the severity of symptoms associated with inflammation of the pancreas (severe pain in the abdomen and back).
- Impotence, decreased sexual drive, absence of menstrual periods.
- Withdrawal symptoms (See section 3 "If you stop taking MST Continus tablets").

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of MST Continus®

-Storage

Keep out of the reach and sight of children. Do not use any tablets after the expiry date which is stated on the blister and carton. Do not store your tablets above 30°C.

-Disposal

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.

Product Description**-What it looks like**

The tablets are all film coated in the following colours: 10mg- golden brown, 30mg- purple. The tablets are marked 10mg, 30mg on one side respectively.

These are available in cartons containing 28 tablets (two blister stripes of 14 tablets).

-Ingredients

The active ingredient is morphine sulfate.

MST Continus® tablets 10mg contains 10mg of morphine sulfate.

MST Continus® tablets 30mg contains 30mg of morphine sulfate.

List of Excipients

Tablet core:

Hydroxyethylcellulose Ph Eur

Purified Water Ph Eur

Cetostearyl Alcohol Ph Eur

Magnesium Stearate Ph Eur

Purified Talc Ph Eur

Lactose Anhydrous (except for 100 mg)

NF

Hypromellose (E464) Ph Eur

Macrogol Ph Eur

The following tablets have the

colourants listed below:

10 mg - Iron oxide (E172), Titanium dioxide (E171)

30 mg - Erythrosine (E127), indigo carmine (E132), sunset yellow (E110), Titanium dioxide (E171)

-MAL number

MST Continus® tablets 10mg -
MAL19920158ACZ

MST Continus® tablets 30mg -
MAL19920157ACZ

Manufacturer

Bard Pharmaceuticals Limited,
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Product Registration Holder

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