

## Package leaflet: Information for the user

### **MST<sup>®</sup> Continus<sup>®</sup> suspension 20 mg, 30 mg and 60 mg**

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

#### **1. What *MST Continus* suspension is and what it is used for**

This suspension has been prescribed for you by your doctor to relieve severe pain over a period of 12 hours. It contains the active ingredient morphine which belongs to a group of medicines called strong analgesics or 'painkillers'.

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

##### **Do not take *MST Continus* suspension if:**

- you are allergic (hypersensitive) to morphine or any of the other ingredients of the suspension (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 suspensions 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 tranylcypromide, 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 this suspension.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking *MST Continus* suspension 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 and coughing;

- 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 suspension (hyperalgesia). Your doctor will decide whether you need a change in dose or a change in strong analgesic (“painkiller”).

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

#### **Other medicines and *MST Continus* suspension**

Concomitant use of opioids and benzodiazepines 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 benzodiazepines or related drugs with opioids the dosage and duration of concomitant treatment should be limited by your doctor.

Please follow your doctor’s dosage recommendations closely. It could be helpful to inform friends and relatives to be aware of sign 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 the suspension with some other medicines, the effect of the suspension or the other medicine may be changed.

The suspension 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...’).

If you need to take a medicine for indigestion, **do not** take it for 2 hours after taking your suspension.

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);
- other strong analgesics or ‘painkillers’ (such as buprenorphine, nalbuphine or pentazocine);
- 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* suspension with alcohol**

Drinking alcohol whilst taking *MST Continus* suspension 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're taking *MST Continus* suspension.

### **Pregnancy, breast-feeding and fertility**

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.

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

### **Driving and using machines**

The suspension 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 suspension, or when changing to a higher dose. If you are affected you should not drive or use machinery.

*MST Continus* suspension contains **Ponceau 4R (E124)** which may cause allergic reactions.

## **3. How to take *MST Continus* suspension**

Always take this medicine exactly as your doctor or pharmacist has told you. The label on your medicine will tell you how much suspension to take and how often. Check with your doctor or pharmacist if you are not sure.

The usual way to take the suspension is to put 10 ml of water into a measuring cup for one sachet.

Cut or tear the top off the sachet. Empty the contents of the sachet into the measuring cup of water. Stir with a spoon for 10 seconds. The suspension contains tiny beads (granules) that will not dissolve. Swallow all the suspension at once. If any suspension remains in the beaker rinse with a little more water and swallow.

If you prefer, you can sprinkle the granules on to cold soft food, such as yogurt.

You must only take the suspension by mouth. **Do not crush, chew or inject the granules.**

***MST Continus* suspension is designed to work properly over 12 hours. The granules must be suspended in water and drunk immediately. If the granules are 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 should take your suspension every 12 hours. For instance, if you take a dose at 8 o'clock in the morning, you should take the next dose at 8 o'clock in the evening.

### **Adults**

The usual starting dose is 20 mg to 30 mg taken every 12 hours. However, the dose will depend on your age, weight and the severity of your pain.

### **Use in children over one year of age**

Children over one year of age can take the suspension. 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 the suspension 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* suspension 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 suspensions with you to show to the doctor.

**If you forget to take *MST Continus* suspension**

If you remember within 4 hours of the time your suspension was due, take it straight away. Take your next dose at your normal time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking *MST Continus* suspension**

You should not suddenly stop taking this suspension unless your doctor tells you to. If you want to stop taking your suspension, 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 the suspension.

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.

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 the suspension.

**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 suspension 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)

- 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 not known** (frequency 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 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* suspension”).
- A need to take increasingly higher doses of *MST Continus* suspension to gain the same level of pain relief (tolerance)
- Withdrawal symptoms in babies born to mothers who have used *MST Continus* suspension 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* suspension**

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 sachet and carton. The expiry date refers to the last day of that month.

Do not store your suspension above 25°C.

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* suspensions contain**

The active substance is morphine sulfate. Each sachet contains 20 mg, 30 mg or 60 mg of morphine sulfate.

The other ingredients are:

- Cationic exchange resin
- Xylitol
- Xanthan gum
- Raspberry flavour
- Ponceau 4R (E124)

### **What *MST Continus* suspensions look like and the contents of the pack**

The suspension sachets contain pink granules with an odour of raspberries. The sachets are coloured as follows: 20 mg - blue, 30 mg – dark purple, 60 mg - orange.

In each box there are 30 sachets.

### **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 suspension  
Reference number: 1688/4/8

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Denmark                    Contalgin®  
Republic of Ireland    MST® Continus®  
United Kingdom        MST® Continus®

**This leaflet was last revised in January 2018.**

*MST® Continus®* suspensions are protected by European Patent (IE) No. 0847273.

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