FRONT

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MST CONTINUS® Controlled Release Tablets

COMPOSITION

MST CONTINUS® Controlled Release Tablets 10 mg are golden brown, film-coated and biconvex. Each tablet contains 10 mg of Morphine Sulfate incorporated within a patented controlled release system. The tablets are marked 10 mg on one side.
MST CONTINUS® Controlled Release Tablets 15 mg are green, film-coated and biconvex. Each tablet contains 15 mg of Morphine Sulfate incorporated within a patented controlled release system. The tablets are marked 15 mg on one side.
MST CONTINUS® Controlled Release Tablets 30 mg are dark purple, film-coated and biconvex. Each tablet contains 30 mg of Morphine Sulfate incorporated within a patented controlled release system. The tablets are marked 30 mg on one side.

THERAPEUTIC PROPERTIES

MST CONTINUS® Controlled Release Tablets have been specifically developed in order to treat severe pain. Treatment with MST CONTINUS® Controlled Release Tablets at 12 hourly intervals ensures relief from severe pain. The simplicity of 12 hourly dosing makes MST CONTINUS® Controlled Release Tablets suitable as a treatment both in hospital and in the patients home. Morphine is an opioid analgesic.
The principal actions of therapeutic value of morphine are analgesia and sedation.

INDICATIONS

MST CONTINUS® Controlled Release Tablets are indicated for the prolonged relief of severe pain.

CONTRAINDICATIONS

Respiratory depression, obstnrctive airway disease, known morphine sensitivity, acute hepatic disease, concurrent administration of monoamine oxydase inhibitors (see also Drug Interactions and Incompatibility). MST CONTINUS® Controlled Release Tablets are not recommended for pediatric use or in pregnancy. Preoperative administration of MST CONTINUS® Controlled Release Tablets is not recommended and is not an approved indication.
Paralytic ileus, asthma bronchiale, gastric emptying. Known hypersensitivity to morphine.

DRUG INTERACTIONS AND INCOMPATIBILITY

Concurrent administration of monoamine oxydase inhibitors or within two weeks of discontinuation of their use is contraindicated. The concomitant use of other central nervous system depressants including sedatives or hypnotics, general anesthetics, phenothiazines, tranquillizers and alcohol may produce additive depressant effects. MST CONTINUS® may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression. Interactive effects resulting in respiratory depression, hypo tension, profound sedation, or coma may result if these drugs are taken with the usual doses of morphine.

PRECAUTIONS

As with all narcotics, a reduction of dosage may be advisable in the elderly, in renal and chronic hepatic disease. Hypothyroidism, adrenocortical insufficiency, prostatic hypertrophy or urethral stricture, acute alcoholism, delirium tremens, hyposcoliosis.
Morphine produces effects which may obscure neurologic signs of further increases in pressure in patients with head injuries.
MST CONTINUS® Controlled Release Tablets like all opioid analgesics, should be administered with caution to patients in circulatory shock, since vasodilatation produced by the drug may further reduce cardiac output and blood pressure.
Morphine may obscure the diagnosis or clinical course in patients with acute abdominal conditions.
Caution should be given in patients about to undergo surgery of the biliary tract, since it may cause spasm of the sphincter of Oddi. Similarly, morphine should be used with caution in patients with acute pancreatitis secondary to biliary tract disease.
Morphine has a well recognized abuse and addiction profile similar to other strong opioids.
Tolerance to analgesic effects may develop upon repeated administration. Physical dependence can develop during repeated administration; cessation of medication or the application of an opioid antagonist may induce withdrawal symptoms.
Morphine may lower the threshold inpatients with a history of epilepsy.
Morphine has to be administered with caution to patients with a history of substance abuse, raised intracranial pressure, hypo tension with hypovolemia, biliary tract disorders, pancreatitis, severe renal dysfunction, severe chronics obstructive lung disease, severe cor pulmonale, severe bronchial asthma and respiratory depression.
Low levels of morphine have been detected in breast milk. Withdrawal symptoms can occur in breast fed infants when maternal administration of morphine sulphate is stopped. Ordinary nursing should not be undertaken while a patient is receiving MST CONTINUS®, since morphine may be excreted in the milk.
As with all morphine preparations, patients who are to undergo condotomy or other pain relieving surgical procedures should not receive MST CONTINUS® Controlled Release Tablets for 24 hours prior to surgery. If further treatment with MST CONTINUS® Controlled Release Tablets is then indicated, the dosage should be adjusted to the new post-operative requirement.

FURTHER INFORMATION

Morphine Sulfate is readily absorbed from the gastrointestinal tract following oral administration.
The patented controlled release system maintains plasma levels of morphine over a period of up to twelve hours and reduces the likelihood of morphine associated side effects. Morphine may impair the ability to drive and use machines.

TRANSFERABILITY

It is not possible to ensure bioequivalence between different controlled release morphine products.
Therefore, it should be emphasized that patients, once titrated to an effective dose, should not be changed from MST CONTINUS® Controlled Release Tablets preparations to other slow, sustained or controlled release morphine preparations without retitration and clinical assessment.

SIDE EFFECTS

The adverse reactions caused by morphine are essentially those observed with other opioid analgesics:
Gastrointestinal : Common : Abdominal pain, anorexia, constipation, dry mouth, dyspepsia, nausea, vomiting.
Uncommon : biliary pain, gastrointestinal disorders, ileus, taste perversion.

APPROVAL ARTWORK — PT. MAHAKAM BETA FARMA

Packdev	Formulasi	Andev	Registrasi	BD	Marketing	Medical	Produksi	QC	QA
06/01/21	04/01/21	04/01/21	23/12 FKU 23/12	N/A		N/A	05/01/21	06/01/21	06 JAN 2021

PT. Mahakam Beta Farma — PACKAGING DEVELOPMENT

Part Description	Insert MST CONTINUS		
IT Code	IT-00000	XXX00	
Supplier	-		
Material	HVS 60 gsm		
Dimension	150 x 240 mm	Bentuk : 2 Face	
Colour / Software	Black	Adobe Illustrator CC 2017	
Draft by / Date	ASR / 22 - 12 - 20		

FINISHING
Lipat, Dilipat (Folded), (lipat 2 tiap bagian)
Panjang dibagi 4

FONT	Jenis Font	Size
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Generik Brand Name :	-	-
Komposisi, dll :	-	-

Revision details :
1. Revisi nama perusahaan Mundhipharmas Email Mba Dewi, Tuesday, 22 Dec 20 (Tgl. 22-12-20)
2.

BACK

Central Nervous System : Common : asthenia, confiision, dizziness, headache, insomnia, involuntary muscle contractions, lightheadness, sedation, somnolenee, thought abrionnalities, asthenia.
Uncommon: agitation, dysphoria, euphoria, hallucinations, malaise, mood changes, paresthesia, respiratory depression, respiratory arrest, seizure, vertigo, vision abnormalities, withdrawal syndrome.
Genitourlnary : Uncommon : amenorrhea, decreased libido, impotence, urinary retention.
Metabolic and Nutritional Uncommon : peripheral edema, pulmonary edema.
Respiratory : Common : apnea, bronchospasm, cough decreased.
Dermatological : Common : rash. Uncommon: urticaria.
General : Common : chills, pruritus, sweating, Uncommon: allergic reaction, anaphylactic/anaphylactoid reactions, drug dependence, facial flushing, hypertonia, miosis, tolerance.

ADMINISTRATION AND DOSAGE
MST CONTINUS® Controlled Release Tablets must swallowed whole and not chewed, broken or crushed.
Taking broken, chewed or crushed MST CONTINUS® Controlled Release Tablets could lead to the rapid release and absorption of a potentially toxic dose of morphine.
MST CONTINUS® Controlled Release Tablets are intended for use in patients who require more than several days continuous treatment with a potent opioid analgesic.
A patient presenting with severe pain uncontrolled by weaker opioid should normally be started on 30 mg MST CONTINUS® Controlled Release Tablets 12 hourly increasing to 60 mg 12 hourly when required. If higher doses are necessary they should be made in 25% - 50% increments.
MST CONTINUS® Controlled Release Tablets should be used twice daily, at 12 hourly intervals. The dosage is dependent upon the severity of the patient's previous history of analgesic requirements.
A patient presenting with severe pain should normally be started on dosage of one or two MST CONTINUS® Controlled Release Tablets 10 mg twice daily. Increasing severity of pain or tolerance to morphine will require increased dosage of MST CONTINUS® tablets using 10 mg, 30 mg, 60 mg, and I00 mg tablets alone or in combination to achieve the desired relief. A patient transferred from other oral morphine preparations normally receive the same total twenty-four hour morphine dosage divided between morning and evening administration. Patients receiving MST CONTINUS® Controlled Release Tablets in place of parenteral morphine should be given a sufiiciently increased dosage to compensate for any reduction in analgesic effects associated with oral administration. Usually such increases requirement is of the order of 50% to 100%. In such patients individual dose adjustment are required.

POST-OPERATIVE PAIN
MST CONTINUS® Controlled Release Tablets are not recommended in the first 24 hours post-operatively; thereafter it is suggested that the following dosage schedule be observed at the physicians discretion.
a. MST CONTINUS® Controlled Release Tablets 20 mg 12 hourly to patients under 70 kilograms.
b. MST CONTINUS® Controlled Release Tablets 30 mg 12 hourly to patients over 70 kilograms.
Supplemental parenteral morphine may be given if required, but with careful attention to the total dosage of morphine and bearing in mind the prolonged effects of morphine in the MST CONTINUS® formulation.
As with all oral morphine preparations, MST CONTINUS® Controlled Release Tablets should be used with caution postoperatively, and particularly in "acute abdomen" and following abdominal surgery.

OVERDOSAGE
Acute overdose with morphine can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, miotic pupils, bradycardia, hypotension and death.
A patent airway must be maintained. The pure opioid antagonists are specific antidotes against symptoms from opioid overdose. Other supportive measures should be employed as needed.
Crushing and taking the contents of a controlled release dosage form leads to the release of the morphine in an immediate fashion; this might result in a fatal overdose.
Treatment of morphine over dosage:
Administer naloxone 0.4 mg intravenously. Repeat at 2 - 3 minute intervals as necessary, or by an infusion of 2 mg in 500 ml normal saline or 5 % dextrose (0.004 mg/ml). This infusion should be run at a rate related to the previous bolus doses administered and should be in accordance with the patient's response. Empty the stomach. A 0.02 % aqueous solution of potassium permanganate may be used for lavage.
Assist respiration, if necessary. Maintain fluid and electrolyte levels. In the case of MST CONTINUS® Controlled Release Tablets, the physician should be aware that Controlled Release Tablets remaining in the intestine will continue release morphine Sulfate for a period of hours.

PRESENTATION
Pack of 6 alustrips @ 10 Controlled Release Tablets.

STORAGE
Store below 30°C and out of children's reach.
On doctor's prescription only.

REGISTRATION NUMBERS
MST CONTINUS® Controlled Release Tablets 10 mg; box 6 strips of 10 tablets: Reg. No. DNL9613701614B1
MST CONTINUS® Controlled Release Tablets 15 mg; box 6 strips of 10 tablets: Reg. No. DNL9613701614C1
MST CONTINUS® Controlled Release Tablets 30 mg; box 6 strips of 10 tablets: Reg. No. DNL1813701614D1

Manufactured by
PT. MAHAKAM BETA FARMA
JAKARTA - INDONESIA
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MST and MST CONTINUS® are Registered Trademarks.
The trademark CONTINUS® distinguishes the controlled release preparation of MUNDIPHARMA and its associates.

HARUS DENGAN RESEP DOKTER

IT-00000 XXX00

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Generik Brand Name : - -
Komposisi, dll : - -

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1. Revisi name perusahaan Mundhipharmas Email Mbo Dewi, Tuesday, 22 Dec 20 (Tgl. 22-12-20)
2.