APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S6

MORPHINE SULPHATE 10 mg/1 mL FRESENIUS solution for injection/infusion.

MORPHINE SULPHATE 15 mg/1 mL FRESENIUS solution for injection/infusion.

Morphine sulphate

Sugar free

Read all of this leaflet carefully before you receive MORPHINE SULPHATE FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or healthcare provider.

What is in this leaflet

1. What **MORPHINE SULPHATE FRESENIUS** is and what it is used for
2. What you need to know before you are given **MORPHINE SULPHATE FRESENIUS**
3. How **MORPHINE SULPHATE FRESENIUS** is given
4. Possible side effects
5. How to store **MORPHINE SULPHATE FRESENIUS**
6. Contents of the pack and other information

1. What MORPHINE SULPHATE FRESENIUS is and what it is used for

MORPHINE SULPHATE FRESENIUS contains the active ingredient morphine sulphate. MORPHINE SULPHATE FRESENIUS is used for the relief of severe and persistent pain where non-narcotic pain relief medication is ineffective.

2. What you need to know before you are given MORPHINE SULPHATE FRESENIUS

MORPHINE SULPHATE FRESENIUS should not be administered to you:

- if you are hypersensitive **(allergic)** to morphine sulphate or any of the other ingredients of MORPHINE SULPHATE FRESENIUS (see section 6 for other ingredients)
- if you are taking medicines used to treat depression known as monoamine oxidase inhibitors (MAOIs) (e.g. phenelzine, tranylcypromine, moclobemide or selegiline) or have taken them in the last 10 days
- if you have difficulty in breathing, shortness of breath, suffer from chronic asthma, chronic lung disease and any obstructive airway disease
- if you have excessive bronchial secretion
- if you are an alcoholic
- if you have convulsive disorders (fits and seizures)
- if you have head injuries or increased pressure in the head
- if you suffer from heart problems
- if you have severe stomach cramps caused by a condition known as biliary colic
- if you are at risk of having a blocked intestine (paralytic ileus)
- if you are suffering from a tumour of the adrenal gland known as a phaeochromocytoma
- if you suffer from severe diarrhoea
- if you are pregnant or breastfeeding.

Warnings and precautions

Special care should be taken with MORPHINE SULPHATE FRESENIUS.

Tell your doctor if you have any of the following medical conditions:

- Hypothyroidism – underactive thyroid gland.
- Adrenocortical insufficiency – undersupply of corticosteroid hormones by the body.
- Impaired kidney or liver function.
- Enlarged prostate.
- Convulsions (fits and seizures).
- Shock (the symptoms of which include sweating, a fast pulse and cold, clammy skin).
- Inflammatory or obstructive bowel disorders.
- Myasthenia gravis – weakness of selected muscles.
- Lung and/or breathing disorders.
- Hypotension – low blood pressure (the symptoms of which include dizziness or light-headedness).
- Biliary tract disease.
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- Loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production.
- 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 interval between doses.

Take special care with MORPHINE SULPHATE FRESENIUS

- Acute generalised exanthematous pustulosis (AGEP) has been reported in association with MORPHINE SULPHATE FRESENIUS 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 MORPHINE SULPHATE FRESENIUS or other opioids. Stop using MORPHINE SULPHATE FRESENIUS 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: MORPHINE SULPHATE FRESENIUS can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). 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 observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.
- 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.

Tolerance, dependence, and addiction

MORPHINE SULPHATE FRESENIUS contains morphine which is an opioid medicine. Repeated use of opioids can result in the medicine being less effective (you become accustomed to it, known as tolerance). Repeated use of MORPHINE SULPHATE FRESENIUS 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, MORPHINE SULPHATE FRESENIUS 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 MORPHINE SULPHATE FRESENIUS, 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.

Other medicines and MORPHINE SULPHATE FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines and MORPHINE SULPHATE FRESENIUS may interfere with each other. Tell your doctor if you are taking or receiving any other medicine, including any non-prescription medicine that you may have purchased from your pharmacy. These include:

- Medicines used to treat depression, e.g. antidepressants.
- Consuming alcohol.
- Medicines use to help you sleep, e.g. sleeping tablets.
- Medicines used to treat anxiety, tension, seizures, panic or sleep disorders, e.g. sedatives.
- Medicines used to control heart rhythm or rate, e.g. mexiletine.

- Medicines used to treat bacterial infections, e.g. ciprofloxacin.
- Medicines used to treat psychiatric or mental disorders (such as phenothiazines).
- Medicines used to treat diarrhoea, e.g. loperamide, kaolin.
- Medicines used as premedication before operations and after heart attacks, e.g. atropine.
- Medicines used to treat nausea and vomiting, e.g. metoclopramide, domperidone.
- Medicines used to treat blood clots, e.g. clopidogrel, prasugrel, ticagrelor.
- Medicines used to treat tuberculosis, e.g. rifampicin.
- Concomitant use of MORPHINE SULPHATE FRESENIUS and sedative medicines such as benzodiazepines or related medicines, 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 MORPHINE SULPHATE FRESENIUS together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

A large number of medicines can interact with MORPHINE SULPHATE FRESENIUS which can significantly alter their effects. These medicines include:

- Gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain)

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

MORPHINE SULPHATE FRESENIUS with alcohol

You should not drink alcohol whilst being given MORPHINE SULPHATE FRESENIUS, as it will increase its effect**.**

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving **MORPHINE SULPHATE FRESENIUS.**

Driving and using machines

MORPHINE SULPHATE FRESENIUS can affect your ability to drive and operate machinery as it may make you sleepy or dizzy.

You should not drive a vehicle or use machinery while **receiving MORPHINE SULPHATE FRESENIUS.**

MORPHINE SULPHATE FRESENIUS contains sodium

MORPHINE SULPHATE FRESENIUS contains less than 1 mmol sodium (23 mg) per 1 mL, that is to say essentially sodium free.

3. How to receive MORPHINE SULPHATE FRESENIUS

You will not be expected to give yourself MORPHINE SULPHATE FRESENIUS. It will be given to you by a person who is qualified to do so.

Your doctor will decide what the dose is and for how long you will receive MORPHINE SULPHATE FRESENIUS. This will vary from patient to patient. It will depend on the reason for receiving MORPHINE SULPHATE FRESENIUS and other factors, such as your physical condition, weight, age as well as other medications that you are taking at the time or after.

For most conditions, MORPHINE SULPHATE FRESENIUS is usually given as a continuous intravenous infusion or in divided doses throughout the day. However, in certain cases a single dose is required for the control of pain.

MORPHINE SULPHATE FRESENIUS injection is administered either

- directly into the muscle (intramuscular), beneath the skin (subcutaneous) or into sheath/membrane surrounding the spinal cord (intrathecal)
- as a slow injection directly into the vein (intravenous) or
- as a slow intravenous infusion directly into the vein on a continuous basis.

If you receive more MORPHINE SULPHATE FRESENIUS than you should

Since a healthcare provider will administer MORPHINE SULPHATE FRESENIUS, he/she will control the dosage.

However, in the event of an overdosage, your doctor will manage the overdosage.

In the unlikely event of an overdose, you may experience any of the following symptoms

- Cold, clammy skin.
- Confusion.
- Convulsions.
- Dizziness.
- Drowsiness.
- Low blood pressure.
- Nervousness or restless.
- Constriction of the pupils.
- Slow heartbeat.
- Slow or troubled breathing.

Missed MORPHINE SULPHATE FRESENIUS doses

Since a healthcare provider will administer MORPHINE SULPHATE FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

MORPHINE SULPHATE FRESENIUS can have side effects.

Not all side effects reported for MORPHINE SULPHATE FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving MORPHINE SULPHATE FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving MORPHINE SULPHATE FRESENIUS and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MORPHINE SULPHATE FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Changes in heart rate and/or an awareness of your heart beating.
- Collapsed lung, wheezing, difficulty in speaking.
- Slow or troubled breathing.
- Convulsions (fits or seizures).
- Withdrawal symptoms or dependence (symptoms may include body aches, shaking, flu-like symptoms, large pupils, an intense feeling of unsatisfaction, anxiety and irritability).
- Severe skin reaction with blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition called Acute Generalised Exanthematous Pustulosis (AGEP).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice anything of the following:

Frequent side effects:

- A feeling of light-headedness (which would be due to lowering of blood pressure) especially when standing,
- Increased sweating,
- Warm sensation of the face,
- Drowsiness,
- Nausea (feeling sick), vomiting (being sick), constipation,
- Unusual tiredness or weakness.

Less frequent side effects:

- Loss of appetite,
- False sense of well-being (unpleasant or uncomfortable mood),
- A feeling of restless,
- Decreased sexual drive, inability to get an erection,
- Sleeplessness,
- Confusion,
- Hallucinations (seeing, feeling or hearing things that are not there),
- Headache,
- Dry mouth,
- Stomach cramps or pain,
- A condition when the bowel does not work properly (paralytic ileus),
- Inflammation of the colon,
- Feeling faint when getting up from a seated position,
- Biliary spasm (spasms in the lower stomach area),

- Rash
- Muscle rigidity (muscle stiffness),
- Trembling or uncontrolled muscle movements,
- Difficulty in urinating,
- Pain and irritation at the site of injection,
- Abdominal pain, including inflamed and irritated pancreas.

Side effects with frequency unknown

- Nightmares or unusual dreams,
- Convulsions
- Blurred vision,
- Dependence,
- Mood changes,
- Sensation of whirling and loss of balance (vertigo),
- Increased sensitivity to pain,
- Feeling of extreme happiness,
- The pupil of your eye becomes smaller,
- Ringing or buzzing in the ears (tinnitus),
- Changes in body temperature from feeling cold to sweating,
- Sleep apnoea (breathing pauses during sleep),
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of MORPHINE SULPHATE FRESENIUS.

Patients are asked to report any suspected adverse reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicines regulatory authority in the country where the product is marketed.

5. How to store MORPHINE SULPHATE FRESENIUS

- Store all medicines out of reach of children.
- MORPHINE SULPHATE FRESENIUS will be stored in the pharmacy or in the hospital wards.
- The injection is protected from light and kept in a cool dry place at or below 25 °C.

6. Contents of the pack and other information

What MORPHINE SULPHATE FRESENIUS contains:

The active substance is morphine sulphate.

Each 1 mL amber ampoule contains 10 mg or 15 mg morphine sulphate.

Other ingredients are: sodium chloride, water for injection, sulphuric acid (for pH adjustment).

What MORPHINE SULPHATE FRESENIUS looks like and contents of the pack:

MORPHINE SULPHATE FRESENIUS is a clear, colourless solution.

A clear, colourless, or almost colourless or light straw to yellow solution.

Containers with 10 x 1 mL amber ampoules.

MORPHINE SULPHATE FRESENIUS 10 mg/1 mL: packed in a 1 mL amber OPC glass ampoule (Type I) with a red ring above the neck.

MORPHINE SULPHATE FRESENIUS 15 mg/1 mL: packed in a 1 mL amber OPC glass ampoule (Type I) with a yellow ring above the neck.

Holder of Certificate of Registration

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Registration numbers

MORPHINE SULPHATE 10 mg/1 mL FRESENIUS: B930 (Act 101/1965).

MORPHINE SULPHATE 15 mg/1 mL FRESENIUS: B931 (Act 101/1965).

Botswana:	15 mg BOT0801158, STA
Kenya:	10 mg H2014/CTD1317/053, POM
Namibia:	NS4, 10 mg 02 1001523 (Act 13/2003)
	NS4, 15 mg 02 1001524 (Act 13/2003)
Zambia:	10 mg 254/017, POM
	15 mg 254/018, POM
Zimbabwe:	15 mg 4.1 Narcotic Analgesics 2006/4.1/4434, N