PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LEVOBUPIVACAINE 2,5 mg/mL FRESENIUS

LEVOBUPIVACAINE 5,0 mg/mL FRESENIUS

LEVOBUPIVACAINE 7,5 mg/mL FRESENIUS

Solution for injection/infusion

Levobupivacaine hydrochloride

Sugar free

Read all of this leaflet carefully before you are given LEVOBUPIVACAINE FRESENIUS, 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, pharmacist, nurse or other healthcare provider.

What is in this leaflet

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

1. What LEVOBUPIVACAINE FRESENIUS is and what it is used for

LEVOBUPIVACAINE FRESENIUS belongs to a group of medicines called local anaesthetics. This type of medicine is used to make an area of the body numb, or free from pain.

Adults:

LEVOBUPIVACAINE FRESENIUS is used as a local anaesthetic to numb parts of the body before major surgery (except for caesarean section) and minor surgery (such as on the eye and mouth). It is also used for pain relief after major surgery.

Children:

LEVOBUPIVACAINE FRESENIUS can also be used in children to numb parts of the body before surgery and for pain relief after minor surgery.

Levobupivacaine has not been tested in children less than 6 months of age.

2. What you need to know before you are given LEVOBUPIVACAINE FRESENIUS

Do not use LEVOBUPIVACAINE FRESENIUS:

- if you are allergic (hypersensitive) to levobupivacaine, to any similar local anaesthetics or to any of the other ingredients of LEVOBUPIVACAINE FRESENIUS (listed in section 6)
- to numb an area by injecting LEVOBUPIVACAINE FRESENIUS into a vein (Bier's block)
- if you have severe kidney or liver problems
- as a type of pain relief given by injection into the area around the neck of the womb (the cervix) during the early stage of labour (paracervical block)
- if you also take medicines for epilepsy (phenytoin, phenobarbital) or rifampicin (medicine for tuberculosis (TB))
- if you also take antifungal medicines such as ketoconazole
- if you have very low blood pressure.

LEVOBUPICAINE 7,5 mg/mL FRESENIUS should not be used for pain relief during labour, or as local anaesthetic for caesarean section.

Warnings and precautions

Talk to your doctor or healthcare provider before being given the injection:

Special care should be taken with LEVOBUPIVACAINE FRESENIUS:

- if you have a heart condition
- if you suffer from diseases of the nervous system
- if you have previously suffered from respiratory arrest after a local anaesthetic injection
- if you are weak or ill
- if you are elderly
- if you have liver disease.

Other medicines and LEVOBUPIVACAINE FRESENIUS

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

In particular, tell them if you are taking or using medicines for:

- local anaesthesia (other amide type local anaesthetics such as lidocaine, bupivacaine)
- irregular heartbeats (such as mexiletine)
- seizures (such as phenytoin, phenobarbital)
- tuberculosis (such as rifampicin)
- fungal infections (such as ketoconazole) since this may affect how long LEVOBUPIVACAINE FRESENIUS stays in your body
- acquired immune deficiency syndrome (AIDS) (such as ritonavir)
- infections (antibiotics such as erythromycin, clarithromycin)

- high blood pressure (such as verapamil)
- acid reflux (such as omeprazole)
- asthma (such as furafylline), since this may affect how long LEVOBUPIVACAINE FRESENIUS stays in your body.

Pregnancy and breastfeeding

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 LEVOBUPIVACAINE FRESENIUS.

LEVOBUPIVACAINE FRESENIUS must not be given for pain relief by injection into the area around the neck of the womb or cervix during childbirth (paracervical block).

LEVOBUPIVACAINE 7,5 mg/mL FRESENIUS should not be given as pain relief during labour or as a local anaesthetic during caesarean section.

The effect of LEVOBUPIVACAINE FRESENIUS on the child during the early stage of pregnancy is not known. Therefore, LEVOBUPIVACAINE FRESENIUS should not be used during the first three months of your pregnancy, unless your doctor thinks it is necessary.

It is not known if levobupivacaine passes into breast milk. The safety of LEVOBUPIVACAINE FRESENIUS in breastfeeding has not been established.

Driving and using machines

The use of LEVOBUPIVACAINE FRESENIUS can have a marked effect on the ability to drive or use machines. You must not drive or operate machinery until all the effects of LEVOBUPIVACAINE FRESENIUS and the immediate effects of surgery have worn off.

Make sure you get advice about this matter from the doctor or nurse who is treating you, before leaving hospital.

LEVOBUPIVACAINE FRESENIUS contains sodium

LEVOBUPIVACAINE FRESENIUS contains 1,57 mmol (or 36 mg) sodium per ampoule of 10 mL solution. To be taken into consideration by patients on a controlled sodium diet.

3. How LEVOBUPIVACAINE FRESENIUS will be given to you

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

LEVOBUPIVACAINE 7,5 mg/mL FRESENIUS can be injected into parts of the body to numb the area that you will have treated, such as the eye, arm or leg.

Apart from the above areas, LEVOBUPIVACAINE 2,5 mg/mL FRESENIUS and LEVOBUPIVACAINE 5 mg/mL FRESENIUS may also be injected through a needle or into a small tube in your back (epidural).

Your doctor and nurse will watch you carefully while you are being given LEVOBUPIVACAINE FRESENIUS.

Usual dosage

The amount of LEVOBUPIVACAINE FRESENIUS you will be given and how often it is given will depend on why it is being used and also on your health, age and weight. The smallest dose that can produce numbness in the required area will be used. The dose will be carefully worked out by your doctor.

If you receive more LEVOBUPIVACAINE FRESENIUS than you should

Since a healthcare provider will administer LEVOBUPIVACAINE FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you get more LEVOBUPIVACAINE FRESENIUS than you should, you may have numbness of the tongue, dizziness, blurred vision, muscle twitching, severe breathing difficulties (including stopping breathing) and even fits (convulsions). If you notice any of these symptoms, tell your doctor immediately.

Sometimes too much LEVOBUPIVACAINE FRESENIUS may also cause low blood pressure, fast or slow heartbeats and changes in your heart rhythm. Your doctor may need to give you other medicines to help stop these symptoms.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

LEVOBUPIVACAINE FRESENIUS can have side effects.

Not all side effects reported for LEVOBUPIVACAINE FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving LEVOBUPIVACAINE FRESENIUS, please consult your healthcare provider for advice.

Your medical condition will be carefully monitored while you are in hospital.

Tell your doctor or nurse immediately if you notice any of the following side effects:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- skin rash, red itchy skin, hives
- chest pain and shortness of breath (cardiac arrest)
- paralysis.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- feeling tired or weak, short of breath, looking pale (these are all signs of anaemia)
- dizziness
- headache
- low blood pressure (feeling faint)
- nausea
- vomiting
- back pain
- foetal distress
- high body temperature (fever)
- pain after surgery

Less frequent side effects

- neurological damage

Side effects with unknown frequency

- fits (convulsions)
- drowsiness
- fainting
- tingling, numbness or other abnormal sensation
- blurred vision

- nerve disorder which can include drooping of the eyelid, small pupil (black centre of the eye), sunken eye socket, sweating and/or redness in one side of the face
- fast, slow or irregular heartbeats, and heart rhythm changes that can be seen on an ECG
- flushing
- temporary cessation of breathing
- sneezing
- numbness of mouth, numbness of the tongue
- lightheadedness
- loss of bladder or bowel control
- prolonged erection of the penis that may be painful
- sweating too much or too little
- muscle twitching
- weak muscles

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 LEVOBUPIVACAINE FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store LEVOBUPIVACAINE FRESENIUS

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package/container.

There are no special storage instructions for LEVOBUPIVACAINE FRESENIUS.

Your doctor will store LEVOBUPIVACAINE FRESENIUS for you.

Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

The solution should be used immediately after opening. Do not use this medicine if you notice visible particles in it.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

These measures will help protect the environment.

6. Contents of the pack and other information

What LEVOBUPIVACAINE FRESENIUS contains

- **The active substance** is levobupivacaine (as levobupivacaine hydrochloride).

1 mL of solution for injection contains 2,5 mg, 5 mg or 7,5 mg levobupivacaine as levobupivacaine hydrochloride.

Each 10 mL ampoule contains 25 mg, 50 mg or 75 mg levobupivacaine as levobupivacaine hydrochloride.

- **The other ingredients** are sodium chloride and water for injection.

This medicine contains an excipient with known effect (sodium). See section 2 for further information. pH 4,0 – 6,0 Osmolarity: 271 - 372 mOsmol/L

What LEVOBUPIVACAINE FRESENIUS looks like and contents of the pack

This medicine is a clear, colourless solution, without any visible particles and packed in polypropylene ampoules (Ovalia) in a sterile blister pack.

Each ampoule contains 10 mL of solution. It is supplied in packs of 5, 10 or 20 ampoules.

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

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LEVOBUPIVACAINE 2,5 mg/mL FRESENIUS:	50/4/0737
LEVOBUPIVACAINE 5 mg/mL FRESENIUS:	50/4/0738
LEVOBUPIVACAINE 7,5 mg/mL FRESENIUS:	50/4/0739

Access to the corresponding Professional Information

The corresponding Professional Information (PI) can be accessed at https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products.