

SCHEDULING STATUS: S4

DEXVICA 5 mg/mL, Solution for injection

Levobupivacaine

Sugar free

Read all of this leaflet carefully before you are given DEXVICA

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

What is in this leaflet

1. What DEXVICA is and what it is used for
2. What you need to know before you use DEXVICA
3. How to use DEXVICA
4. Possible side effects
5. How to store DEXVICA
6. Contents of the pack and other information

1. What DEXVICA is and what it is used for

DEXVICA 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:

DEXVICA is used as a local anaesthetic to numb parts of the body before major surgery (for example as an epidural for caesarean section) and minor surgery (such as on the mouth).

It is also used for pain relief:

- after major surgery
- during childbirth

Children

DEXVICA can also be used with children to numb parts of the body before surgery and for pain relief after minor surgery, such as the repair of a groin hernia.

2. What you need to know before you use DEXVICA

DEXVICA should not be administered to you:

- if you are hypersensitive (allergic) to levobupivacaine to any similar local anaesthetics or any of the other ingredients of DEXVICA (listed in section 6).
- to numb an area by injecting DEXVICA into a vein
- if you have severe kidney or liver impairment
- if you have very low blood pressure
- 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 use medicines that induce CYP3A4 enzyme, such as phenytoin, phenobarbital and rifampicin
- if you use medicines that inhibit CYP3A4 enzyme, such as azole antimycotics (e.g., ketoconazole).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection.

Special care should be taken with DEXVICA:

- if you if you have a heart condition
- if you have very low blood pressure

- if you suffer from diseases of the nervous system
- if you have liver disease.

Other medicines and DEXVICA

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

In particular, tell your healthcare provider if you are taking medicines for:

- irregular heartbeats (such as mexiletine)
- fungal infections (such as ketoconazole) since this may affect how long DEXVICA stays in your body
- asthma (such as theophylline or furafylline) since this may affect how long DEXVICA stays in your body.
- local anaesthetics or similar medicines – the combined effects may be harmful
- epilepsy (such as phenytoin, phenobarbital), tuberculosis (such as rifampicin) - DEXVICA should not be administered to you (see section 2).
- HIV (such as ritonavir), bacterial infection (such as erythromycin, clarithromycin), heart conditions (such as verapamil) - it can increase the risk of toxicity of DEXVICA
- stomach ulcer (such as omeprazole) - it may speed up the breakdown of DEXVICA

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 being administered this medicine.

DEXVICA should not be administered to you if you are pregnant or breastfeeding your baby.

There is no information on how DEXVICA affects fertility.

Driving and using machines

It is not always possible to predict to what extent DEXVICA may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which DEXVICA affects you.

DEXVICA contains sodium chloride

DEXVICA contains 3,5 mg/mL sodium in the bag or ampoule solution to be taken into consideration by patients on a controlled sodium diet.

DEXVICA contains 35 mg sodium (main component of cooking/table salt) in each 10 mL ampoule. This is equivalent to 0,18 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use DEXVICA

Your doctor will give you DEXVICA by injection through a needle or into a small tube in your back (epidural). DEXVICA can also be injected into other parts of the body to numb the area that you will have treated, such as the arm or leg.

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

The amount of DEXVICA 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.

When DEXVICA is used for pain relief during labour or for childbirth by caesarean section (an epidural), the dose used should be particularly carefully controlled.

If you get more DEXVICA than you should

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

If you receive more DEXVICA 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 DEXVICA 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.

If you forget to use DEXVICA

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

4. Possible side effects

DEXVICA can have side effects.

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

If any of the following happens, stop using DEXVICA 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 DEXVICA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately 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)
- problems (distress) for an unborn child

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness
- headache
- low blood pressure
- nausea
- vomiting
- back pain
- high body temperature (fever)
- pain after surgery

Side effects with unknown frequency:

- fits (convulsions)
- loss of consciousness
- tingling, numbness or other abnormal sensation
- paralysis
- paralysis that affects your ability to move the lower half of your body
- drowsiness
- 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
- heart block or heart stopping
- fast, slow or irregular heartbeats, and heart rhythm changes that can be seen on an ECG
- localised tingling
- absence of breathing, temporary cessation of breathing, especially during sleep, sneezing
- numbness of the tongue
- hives, swelling underneath the skin, excessive sweating, inability to sweat normally, skin redness and skin itching
- muscle weakness or twitching
- loss of bladder or bowel control
- prolonged erection of the penis that may be painful

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 DEXVICA.

5. How to store DEXVICA

Store all medicines out of reach of children.

Store at or below 30 °C in a cool place.

Do not use this medicine 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.

It is for single use only. Any unused portion should be discarded.

The solution should not be used if there are visible particles in it.

6. Contents of the pack and other information

What DEXVICA contains

- The active substance is levobupivacaine (as hydrochloride monohydrate).
- DEXVICA 5 mg/mL solution for injection: each mL contains 5 mg levobupivacaine (as hydrochloride monohydrate). Each ampoule contains 50 mg levobupivacaine in 10 mL.
- The other ingredients are sodium chloride, hydrochloric acid 10 %, sodium hydroxide and water for injection.

What DEXVICA looks like and contents of the pack

It is a clear, colourless solution, free of visible particles in Type I clear glass ampoules packed in PVC tray covered with medical paper.

Each box contains 5 ampoules of 10 mL (box of 5's).

Holder of Certificate of Registration

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Equity Pharmaceuticals (Pty) Ltd.

DEXVICA, Solution for injection

Each 1 mL contains levobupivacaine hydrochloride
monohydrate equivalent to 5 mg levobupivacaine

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Approved Patient Information Leaflet

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