1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

DIRADEX, 200 mg/2 ml, Solution for Injection

Sugammadex

Sugar free

Read all of this leaflet carefully before you are given DIRADEX

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

1. What DIRADEX is and what it is used for

DIRADEX belongs to a group of medicines called antidotes (medicine taken or given to counteract the effects of another medicine).

DIRADEX is used to speed up the recovery of your muscles after an operation to allow you to breathe on your own again earlier. It does this by combining with the rocuronium bromide or vecuronium bromide in your body. It can be used in adults whenever rocuronium bromide or vecuronium bromide is used and in children (above 7 years of age) and adolescents when rocuronium bromide is used for a moderate level of relaxation.

What you need to know before you are given DIRADEX

DIRADEX should not be administered to you:

- if you are hypersensitive (allergic) to sugammadex or any of the other ingredients of DIRADEX (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before being given DIRADEX:

Special care should be taken with DIRADEX:

- if you have kidney problems (the signs may include feeling tired, bruising easily and passing water (urinating) less often)
- if you experience slowness of heart beat after being given DIRADEX
- if you are taking any blood thinning medication for a pre-existing or co-morbid condition
- if you suffer from any heart condition
- if you have liver problems
- Fluid retention (oedema)

Children and adolescents

Immediate reversal in children and adolescents has not been investigated and is therefore not recommended.

DIRADEX can only be used in certain procedures and should not be used in children under 7 years of age.

Other medicines and DIRADEX

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

Toremifene (used to treat breast cancer), if taken on the same day, may delay the effects of DIRADEX.

The intravenous administration of fusidic acid (an antibiotic), may delay the effects of DIRADEX.

DIRADEX may decrease the effectiveness of hormonal oral contraceptives such as progestrone and oestrogens. If you are taking hormonal contraceptives on the same day as DIRADEX is given to you, follow the instructions for a missed dose in the hormonal contraceptives package insert. In the case of non-oral hormonal contraceptives, an additional non-hormonal contraceptive method must be used for the next 7 days.

Effect on blood tests:

In general, DIRADEX does not have an effect on laboratory tests. However, it may affect the results of a blood test for a hormone called progesterone. Talk to your doctor if your progesterone levels need to be tested on the same day you receive DIRADEX.

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 health care provider for advice before being given this medicine.

It is not advisable to receive DIRADEX when you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent DIRADEX may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which DIRADEX affects you.

DIRADEX contains up to 9,7 mg sodium per mL, equivalent to 0,5 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

2. How DIRADEX is given

Do not share medicines prescribed for you with any other person.

Injection

DIRADEX may be administered into your vein as a single dose (single bolus injction) or into an exisitng IV line.

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

If you are given more DIRADEX than you should receive:

Since a health care provider will administer DIRADEX, he/she will control the dosage.

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

If you forget to take DIRADEX

Since a health care provider will administer DIRADEX, it is unlikely that the dose will be missed.

3. Possible side effects

DIRADEX can have side effects.

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

If any of the following happens, stop taking/using DIRADEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 DIRADEX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- cough
- airway difficulties that may include coughing or moving as if you are waking or taking a breath;
- light anaesthesia – you may start to come of out of deep sleep, so need more anaesthesia.
- This might cause you to move or cough at the end of the operation;
- complications during your procedure such as changes in heart rate, coughing or moving;
- decreased blood pressure due to surgical procedure

Less frequent side effects:

- shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems;
- return of muscle relaxation after the operation
- severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when DIRADEX is administered.

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 DIRADEX.

4. How to store DIRADEX

Store all medicines out of reach of children.

Do not store above 30 °C. Store below 30 °C. Do not freeze. Keep the vial in the outer carton in order to protect from light.

5. Contents of the pack and other information

What DIRADEX contains

The active substance is sugammadex sodium.

The other ingredients are sodium hydroxide, diluted hydrochloric acid, water for injection and nitrogen.

What DIRADEX looks like and contents of the pack

DIRADEX is packaged in a 2 ml clear, borosilicate, type I glass vial with a chlorobutyl rubber stopper and a pale brown aluminium plastic cap.

Holder of Certificate of Registration

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Not applicable

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