Dimension：180*580mm

成品线(Keyline)

文字图案区域（Text area）

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
2. What you need to know before you are given DIRADEX
3. How DIRADEX is given
4. Possible side effects
5. How to store DIRADEX
6. Contents of the pack and other information

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.

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.

The vials are packed in a carton containing 10 vials.

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

DIRADEX, 200 mg/2 ml
Oplossing vir inspuiting
Sugammadeks
Suikervry

Lees hierdie hele blad noukeurig deur voordat DIRADEX aan u gegee word.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.

1. Wat DIRADEX is en waarvoor dit gebruik word
2. Wat u moet weet voordat u DIRADEX kry
3. Hoe DIRADEX gegee word
4. Moontlike newe-effekte
5. Hoe om DIRADEX te bêre
6. Inhoud van die pak en ander inligting

1. Wat DIRADEX is en waarvoor dit gebruik word
DIRADEX behoort aan 'n groep medisyne wat teenmiddels genoem word (medisyne wat gebruik word om die effekte van ander medisyne teen te werk).

DIRADEX word gebruik om die herstel van u spiere na 'n operasie te bespoedig sodat u vroeër weer op u eie kan asemhaal. Dit doen dit deur aan die rokuroniumbromied of vekuroniumbromied in u liggaam te bind. Dit kan in volwassenes gebruik word wanneer rokuroniumbromied of vekuroniumbromied gebruik word en in kinders (bo 7 jaar oud) en adolessente wanneer rokuroniumbromied vir 'n matige vlak van ontspanning gebruik word.

Wat u moet weet voordat u DIRADEX kry
DIRADEX moet nie aan u gegee word nie:
- as u hipersensitief (allergies) vir sugammadeks of vir enige van die ander bestanddele van DIRADEX (gelys in afdeling 6) is.

Waarskuwings en voorsorgmaatreëls
Sê vir u dokter of gesondheidsorgverskaffer voordat u DIRADEX kry:
Wees besonder versigtig met DIRADEX:
- as u nierprobleme het (die tekens kan wees dat u moeg voel, maklik kneus en minder gereeld urineer).
- as u 'n stadige hartklop ervaar nadat u DIRADEX gekry het.
- as u enige bloedverdunners gebruik vir 'n voorafbestaande of komorbiede toestand.
- as u aan enige harttoestand ly.
- as u lewerprobleme het.
- as u vloeistofretensie (edeem) het.

Kinders en adolessente
Onmiddellike omkering in kinders en adolessente is nie ondersoek nie en word dus nie aanbeveel nie.

DIRADEX kan slegs in sekere prosedures gebruik word en moet nie vir kinders onder 7 jaar oud gebruik word nie.

Ander medisyne en DIRADEX
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder alle aanvullende of tradisionele medisyne).

Toremifeen (vir borskanker), indien dit op dieselfde dag geneem word, kan die effekte van DIRADEX vertraag.

Die binneaarse toediening van fusidiensuur ('n antibiotikum) kan die effekte van DIRADEX vertraag.

DIRADEX kan die doeltreffendheid van hormonale orale voorbehoedmiddels soos progesteroon en estrogeen verlaag. As u hormonale voorbehoedmiddels op dieselfde dag drink as wat DIRADEX aan u gegee word, moet u die instruksies vir 'n oorgeslane dosis in die voubiljet van die hormonale voorbehoedmiddel volg. In die geval van nie-orale hormonale voorbehoedmiddels, moet 'n addisionele nie-hormonale voorbehoedmiddel vir die volgende 7 dae gebruik word.

Effek op bloedtoetse
Oor die algemeen het DIRADEX nie 'n effek op laboratoriumtoetse nie. Dit kan egter die resultate van 'n bloedtoets vir 'n hormoon genaamd progesteroon beïnvloed. Praat met u dokter as u progesteroonvlakke getoets moet word op dieselfde dag as wat u DIRADEX kry.

Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat hierdie medisyne aan u gegee word.

Dit is nie raadsaam om DIRADEX te kry as u swanger is of u baba borsvoed nie.

Motorbestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel tot watter mate DIRADEX met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u totdat u weet tot watter mate DIRADEX u aantas u nie betrokke raak by aktiwiteite wat verstandelike wakkerheid, goeie oordeel en/of gesonde koördinasie en visie vereis nie, bv. motorbestuur, ry, vlieg, seil en/of masjiene/toerusting hanteer nie.

DIRADEX bevat 9,7 mg natrium per ml, gelykstaande aan 0,5 % van die WGO se aanbevole maksimum daaglikse inname van 2 g natrium vir 'n volwassene.

2. Hoe DIRADEX gegee word
Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

Inspuiting

DIRADEX kan as 'n enkele dosis (enkele bolusinspuiting) in u aar of in 'n bestaande IV-lyn gegee word.

Dit sal nie van u verwag word om DIRADEX aan uself te gee nie. Dit sal aan u gegee word deur 'n persoon wat gekwalifiseerd is om dit te doen.

As u meer DIRADEX gekry het as wat u moes
Aangesien 'n gesondheidsorgverskaffer DIRADEX sal gee, sal hy/sy die dosis beheer. In geval van oordosering, sal u dokter die oordosering egter bestuur.

As u vergeet om DIRADEX te kry
Aangesien 'n gesondheidsorgverskaffer DIRADEX sal gee, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

Moontlike newe-effekte
DIRADEX kan newe-effekte veroorsaak.

Nie al die newe-effekte wat vir DIRADEX aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u newe-effekte ervaar terwyl u DIRADEX kry, moet u u dokter, apteker of ander gesondheidspraktisyn asseblief om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om DIRADEX te gebruik en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk
- floutes

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie op DIRADEX gehad het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê vir u dokter as u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- hoes
- lugwegprobleme wat hoes kan wees of beweging asof mens wakker word of 'n asemteug neem
- ligte narkose – u kan dalk uit diepe slaap begin kom, en moet dus moet meer narkose kry
- dit kan veroorsaak dat u aan die einde van die operasie beweeg of hoes
- komplikasies tydens u prosedure soos veranderinge in hartklop, hoes of beweging
- lae bloeddruk as gevolg van chirurgiese prosedure

Newe-effekte wat minder dikwels voorkom:
- kortasemheid as gevolg van spierkrampe van die lugweë (brongospasma) het voorgekom in pasiënte met 'n geskiedenis van longprobleme
- terugkeer van spierverslapping na die operasie
- erge verstadiging van die hart en verstadiging van die hart tot hartstilstand kan voorkom wanneer DIRADEX gegee word

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegkundige as u newe-effekte ervaar. U kan newe-effekte ook by SAHPRA aanmeld via die Med Safety-toep (Medsafety X SAHPRA) en eReporting- platform (who-umc.org) wat op SAHPRA se webwerf gekry kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van DIRADEX te gee.

4. Hoe om DIRADEX te bêre

Hou alle medisyne buite bereik van kinders.

Moenie bo 30 °C bêre nie. Bêre onder 30 °C. Moenie vries nie. Hou die flessie in die buitenste karton om dit teen lig te beskerm.

5. Inhoud van die pak en ander inligting oor wat DIRADEX bevat

Die aktiewe bestanddeel is natriumsugammadeks.

Die ander bestanddele is natriumhidroksied, verdunde soutsuur, water vir inspuiting en stikstof.

Hoe DIRADEX lyk en die inhoud van die pakkie

DIRADEX word verpak in 'n flessie van 2 ml van deursigtige, tipe I-borosilikaatglas met 'n chloorbutielrubberprop en 'n ligbruin aluminiumplastiekdoppie.

Die flessies word verpak in 'n kartondosie wat 10 flessies bevat.

Houer van die registrasiesertifikaat
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Hierdie blad is laas hersien in
Nie toepaslik nie

Registrasienommer
56/2.11/1211