Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: TEMADEX 200 & 500 Dosage form & strength: solution for injection, 1 ml contains sugammadex sodium equivalent to 100 mg sugammadex.

SCHEDULING STATUS:

S4

TEMADEX 200 (solution for injection)

TEMADEX 500 (solution for injection)

Sugammadex sodium equivalent to sugammadex

Read all of this leaflet carefully before you are given TEMADEX:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TEMADEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT TEMADEX IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE TEMADEX IS GIVEN

3. HOW TEMADEX IS GIVEN

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE TEMADEX

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1.WHAT TEMADEX IS AND WHAT IT IS USED FOR:

TEMADEX 100 mg/ml solution for injection contains the active substance sugammadex.

TEMADEX is a *Selective Relaxant Binding Agent* since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide.

When you have some types of operations, your muscles must be completely relaxed. This makes it easier for the surgeon to do the operation. For this, the general anaesthetic you are given includes medicines to make your muscles relax. These are called *muscle relaxants*, and examples include rocuronium bromide and vecuronium

bromide. Because these medicines also make your breathing muscles relax, you need help to breathe (artificial ventilation) during and after your operation until you can breathe on your own again.

TEMADEX 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.

2. WHAT YOU NEED TO KNOW BEFORE TEMADEX IS GIVEN:

You should not be given TEMADEX:

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

Tell your anaesthetist if this applies to you.

Warnings and precautions:

Talk to your anaesthetist before TEMADEX is given:

- If you have kidney disease or had it in the past. This is important as TEMADEX is removed from your body by the kidneys.
- If you have liver disease or have had it in the past.
- If you have fluid retention (oedema).
- If you have diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or are using anticoagulation medication.

Children and adolescents:

TEMADEX is not recommended for children younger than 7 years of age.

Other medicines and TEMADEX:

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

TEMADEX may affect other medicines or be affected by them.

Some medicines reduce the effect of TEMADEX:

It is especially important to tell your anaesthetist if you have recently taken:

- Toremifene (used to treat breast cancer).
- Fusidic acid (an antibiotic).

TEMADEX can affect hormonal contraceptives:

TEMADEX can make hormonal contraceptives - including the 'Pill', vaginal ring, implants or a hormonal Intra Uterine System (IUS) - less effective because it reduces how much you get of the progestogen hormone. The amount of progestogen lost by using TEMADEX is about the same as missing one oral contraceptive Pill.

→ If you are taking the **Pill** on the same day as TEMADEX is given to you, follow the instructions for a missed dose in the Pill's patient information leaflet.

→ If you are using **other** hormonal contraceptives (for example a vaginal ring, implant or IUS) you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days and follow the advice in the patient information leaflet.

Effect on blood tests:

In general, TEMADEX 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 TEMADEX.

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 you are given TEMADEX.

It is not known whether sugammadex can pass into breast milk.

Driving and using machines:

TEMADEX has no known influence on your ability to drive and use machines.

It is not always possible to predict to what extent TEMADEX may interfere with your daily activities. You should

ensure that you do not engage in the above activities until you are aware of the measure to which TEMADEX affects you.

3. HOW TEMADEX IS GIVEN:

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

TEMADEX will be given to you by your anaesthetist, or under care of your anaesthetist.

The dose:

Your anaesthetist will work out the dose of TEMADEX you need based on:

- your weight;
- how much the muscle relaxant medicine is still affecting you.

The usual dose is 2 to 4 mg per kg body weight. A dose of 16 mg/kg can be used in adults if urgent recovery from muscle relaxation is needed.

The dose of TEMADEX for children older than 7 years of age is 2 mg/kg.

How TEMADEX is given:

TEMADEX will be given to you by your anaesthetist. It is given as a single injection through an intravenous line.

If more TEMADEX is given to you than recommended:

As your anaesthetist will be monitoring your condition carefully, it is unlikely that you will be given too much TEMADEX. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use TEMADEX:

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

If you have any further questions on the use of TEMADEX, ask your healthcare professional.

4. POSSIBLE SIDE EFFECTS:

TEMADEX can have side effects.

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

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

- Allergic (drug hypersensitivity) reactions- such as rash, red skin, swelling of your tongue and/or throat, shortness of breath, changes in blood pressure or heart rate, sometimes resulting in a serious decrease of blood pressure. Severe allergic or allergic-like reactions can be life threatening.

These are all very serious side effects. If you have them, you may have had a serious reaction to TEMADEX. You may need urgent medical attention.

If any side effects occur while you are under anaesthesia, it will be seen and treated by your anaesthetist.

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 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.

Frequency unknown:

- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when TEMADEX 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 **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TEMADEX.

5. HOW TO STORE TEMADEX:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store below 25 °C.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

After first opening and dilution, store at 2 to 8 ℃ and use within 24 hours.

Do not use after the expiry date stated on the carton and label.

Return all unused medicine to your pharmacist.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TEMADEX contains:

The active substance is sugammadex.

1 ml solution for injection contains sugammadex sodium equivalent to 100 mg sugammadex.

Each vial of 2 ml contains sugammadex sodium equivalent to 200 mg sugammadex.

Each vial of 5 ml contains sugammadex sodium equivalent to 500 mg sugammadex.

The other ingredients are water for injection, hydrochloric acid and/or sodium hydroxide.

What TEMADEX looks like and contents of the pack:

TEMADEX is a clear and colourless to slightly yellow-brown solution for injection.

The solution is supplied as a single-dose, in a colourless type I glass vial, closed with type I rubber stopper and sealed by an aluminium cap with coloured polypropylene disk.

It comes in two different pack sizes, containing either 10 vials with 2 ml or 10 vials with 5 ml solution for injection. Packed in an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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