Patient information leaflet

SCHEDULING STATUS:

S4

SUMABID 100 IV

100 mg/mL solution for injection

(sugammadex)

(Sugar free)

This product contains 9,7 mg sodium (see section 6)

Read all of this leaflet carefully before you are given SUMABID.

- 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.

What is in this leaflet

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

1. What SUMABID is and what it is used for

What SUMABID is

SUMABID contains the active substance sugammadex. Sugammadex is considered to be a *Selective Relaxant Binding Agent* since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide.

What SUMABID is used for

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.

Sugammadex 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 and adolescents (aged ≥7 years) when rocuronium bromide is used for a moderate level of relaxation.

2. What you need to know before SUMABID is given to you

SUMABID should not be given to you:

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

Tell your doctor if this applies to you.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have kidney disease or had in the past. This is important as sugammadex 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 are on a controlled salt diet.
- if you have diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or anticoagulation medication.

Children and adolescents

This medicine is not recommended for children less than 7 years of age.

Other medicines and SUMABID

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

Sugammadex may affect other medicines or be affected by them.

Some medicines reduce the effect of sugammadex

It is especially important that you tell your doctor or pharmacist if you have recently taken:

- toremifene (used to treat breast cancer).
- fusidic acid (an antibiotic).

Sugammadex can affect hormonal contraceptives

- Sugammadex can make hormonal contraceptives - including the 'Pill', vaginal ring, implants or a hormonal IntraUterine System (IUS) - less effective because it reduces how much you get of the progestogen hormone. The amount of progestogen lost by using sugammadex is about the same as missing one oral contraceptive Pill.
    - If you are taking the **Pill** on the same day as sugammadex is given to you, follow the instructions for a missed dose in the Pill's package insert.

- 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 package insert.

Effects on blood tests

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

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.

You may still be given **SUMABID V 100**, but you need to discuss it first. It is not known whether sugammadex can pass into breast milk. Your doctor will help you decide whether to stop breast-feeding, or whether to abstain from sugammadex therapy, considering the benefit of breast-feeding to the baby and the benefit of sugammadex to the mother.

Driving and using machines

SUMABID has no known influence on your ability to drive and use machines. It is not always possible to predict to what extent SUMABID IV 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 SUMABID IV affects you.

3. How SUMABID is given

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

The anaesthetist or healthcare professional will administer your correct dose.

The dose

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

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

How **SUMABID** is given

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

Your doctor will tell you how long your treatment with **SUMABID** will last.

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

If more SUMABID 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 **SUMABID**. However, in the event of overdosage your doctor will manage the overdose.

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

If you forget to use SUMABID

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

If you stop using SUMABID

If treatment with **SUMABID** is interrupted, recovery of your muscles after an operation might not happen fast enough to allow you to breathe earlier on your own again.

4. Possible side effects

SUMABID can have side effects.

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

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

Serious side effects

If any of the following happens, tell your doctor immediately or go to the casualty department of your nearest hospital:

Less frequent side effects

- Allergic (drug hypersensitivity) reactions - such as a 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. Allergic reactions were reported more commonly in healthy, conscious volunteers

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent side effects

- Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when **SUMABID** is administered

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

Other side effects

Tell your doctor as soon as possible about any of the following side effects:

Frequent side effects

- Cough
- A temporary unpleasant taste in your mouth
- 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 the surgical procedure
- Your muscles may be weakened for longer than expected after the operation.

Less frequent side effects

- Return of muscle relaxation after the operation
- Being awake during the operation (anaesthesia awareness).

Other side effects not listed above may occur in some patients. 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. Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000. By reporting side effects, you can help provide more information on the safety of **SUMABID**.

5. How to store SUMABID

Store all medicines out opf reach of children

Solution for injection:

Store at or below 25°C.

Do not freeze.

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

Diluted solution for injection:

Store at 2 °C to 8 °C or below 25 °C.

6. Contents of the pack and other information

What SUMABID contains

The active ingredient is sugammadex.

The other ingredients are:

Water for Injection

Hydrogen Chloride or Sodium Hydroxide

Nitrogen

What SUMABID looks like and contents of the pack

SUMABID is packed in glass type I vials with a bromobutyl ruber stopper. On the vial an aluminium cap with flip top are applied. The aluminium cap is applied to tightly fix the rubber stopper to the glass vial.

Pack size: 10 vials of 2 mL packed in a carton box.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

a Sun Pharma company

14 Lautre Road, Stormill, Ext.1,

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This leaflet was last revised in:

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Registration numbers

56/34/0244

Namibia Only:	NS2
SUMABID 100 IV: 04/20.1.1/0602	

Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: https://sunpharma.com/south-africa-products/

Pasiëntinligtingsblad

SKEDULERINGSTATUS:

S4

SUMABID 100 IV

100 mg/mL oplossing vir inspuiting

(sugammadex)

(Suikervry)

Hierdie produk bevat 9,7 mg natrium (sien afdeling 6)

Lees hierdie hele inligtingstuk noukeurig deur voordat SUMABID aan jou toegedien word**.**

- Hou hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees.
- Vra asseblief vir jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vrae het.

Wat is in hierdie inligtingsblad

1. Wat **SUMABID** is en waarvoor dit gebruik word
2. Wat jy moet weet voordat **SUMABID** aan jou toegedien word
3. Hoe **SUMABID** gebruik word
4. Moontlike newe-effekte
5. Hoe om **SUMABID** te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat SUMABID is en waarvoor dit gebruik word

Wat SUMABID is

SUMABID bevat die aktiewe bestanddeel sugammadex. Sugammadex word beskou as 'n *selektiewe spierverslappingsbindmiddel* aangesien dit slegs werk saam met spesifieke spierverslappers, rokuroniumbromied of vekuroniumbromied.

Waarvoor SUMABID gebruik word

Wanneer jy sekere soorte operasies ondergaan, moet jou spiere volledig verslap wees. Dit maak dit makliker vir die chirurg om die operasie uit te voer. Hiervoor sluit die algemene narkose wat aan jou toegedien word medisyne in wat jou spiere laat verslap. Hierdie word *spierverslappers* genoem en voorbeelde sluit rokuroniumbromied en vekuroniumbromied in. Omdat hierdie medisyne ook veroorsaak dat jou asemhalingspiere verslap, benodig jy hulp om asem te haal (kunsmatige ventilasie) tydens en ná jou operasie totdat jy weer op jou eie kan asemhaal.

Sugammadex word gebruik om herstel van jou spiere ná 'n operasie te bespoedig sodat jy vroeër weer op jou eie kan asemhaal. Dit werk deur te verbind met die rokuroniumbromied of vekuroniumbromied in jou liggaam. Dit kan by volwassenes gebruik word wanneer rokuroniumbromied of vekuroniumbromied gebruik word en by kinders en adolessente (ouderdom ≥ 7 jaar) wanneer rokuroniumbromied vir 'n matige vlak van verslapping gebruik word.

2. Wat jy moet weet voordat SUMABID aan jou toegedien word

SUMABID moet nie aan jou toegedien word nie:

- As jy hipersensitief (allergies) is vir sugammadex of enige van die ander bestanddele van **SUMABID IV** (gelys in afdeling 6).

Lig jou dokter in indien dit op jou van toepassing is.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat die inspuiting aan jou toegedien

word:

- as jy niersiekte het of in die verlede gehad het. Dit is belangrik aangesien sugammadex deur die niere uit jou liggaam verwyder word.
- as jy lewersiekte het of dit in die verlede gehad het.
- as jy vogretensie (edeem) het.
- as jy op 'n beheerde soutdieet is.
- as jy siektetoestande het wat bekend is daarvoor dat dit 'n verhoogde risiko van bloeding veroorsaak (versteurings van bloedstolling) of antistollingsmedikasie gebruik.

Kinders en adolessente

Hierdie medisyne word nie aanbeveel vir kinders onder die ouderdom van 7 jaar nie.

Ander medisyne en SUMABID

Lig jou gesondheidsorgverskaffer altyd in as jy enige ander medisyne gebruik (dit sluit alle komplementêre of tradisionele medisyne in).

Sugammadex kan ander medisyne beïnvloed of daardeur beïnvloed word.

Sommige medisyne verminder die effek van sugammadex

Dit is veral belangrik dat jy jou dokter of apteker inlig as jy onlangs die volgende geneem het:

- toremifeen (gebruik om borskanker te behandel).
- fusidiensuur ('n antibiotikum).

Sugammadex kan hormonale voorbehoedmiddels beïnvloed.

- Sugammadex kan hormonale voorbehoedmiddels – insluitend die ‘Pil’, vaginale ring, inplantings of ‘n hormonale IntraUterienstelsel (IUS) - minder effektief maak omdat dit die hoeveelheid progestogeenhormoon wat jy verkry, verminder. Die hoeveelheid progestogeen wat verlore gaan deur sugammadex te gebruik, is omtrent dieselfde as om een orale voorbehoedpil oor te slaan.

- As jy die 'Pil' op dieselfde dag neem as wat sugammadex aan jou toegedien word, moet jy die aanwysings vir 'n oorgeslaande dosis op die 'Pil' se inligtingsblad volg
- As jy "ander" hormonale voorbehoedmiddels (byvoorbeeld 'n vaginale ring, inplantaat of IUS) gebruik, moet jy vir die volgende 7 dae 'n addisionele nie-hormonale voorbehoedmetode (soos 'n kondoom) gebruik en die advies in die inligtingsblad volg.

Effekte op bloedtoetse

Oor die algemeen het sugammadex nie 'n effek op laboratoriumtoetse nie. Dit kan egter die resultate van 'n bloedtoets vir 'n hormoon wat progesteroon genoem word en sommige bloedstollingstoetse beïnvloed. Praat met jou dokter as jou progesteroonvlakke getoets moet word op dieselfde dag as wat sugammadex aan jou toegedien word.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, vermoed dat jy swanger mag wees of as jy beplan om swanger te raak, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat hierdie medisyne aan jou toegedien word.

SUMABID IV 100 kan nog steeds aan jou toegedien word, maar jy moet dit eers bespreek.

Dit is nie bekend of sugammadex in borsmelk uitgeskei word nie.

Jou dokter sal jou help om te besluit of jy moet ophou borsvoed, of om van sugammadex -behandeling weerhou te word, met inagneming van die voordeel van borsvoeding vir die baba en die voordeel van sugammadex vir die moeder.

Bestuur en gebruik van masjinerie

SUMABID IV het geen bekende invloed op jou vermoë om te bestuur en masjinerie te hanteer nie. Dit is nie altyd moontlik om te voorspel tot watter mate **SUMABID IV** jou daaglikse aktiwiteite kan inmeng nie. Jy moet verseker dat jy nie by die bogenoemde

aktiwiteite betrokke raak totdat jy bewus is van die mate waarin **SUMABID IV** jou beïnvloed nie.

3. Hoe SUMABID toegedien word

SUMABID sal deur ‘n narkotiseur aan jou toegedien word, of onder die toesig van jou narkotiseur.

Die narkotiseur of professionele gesondheidswerker sal jou korrekte dosis toedien.

Die dosis

Jou narkotiseur sal die dosis van **SUMABID** wat jy benodig bepaal op grond van die volgende:

- jou gewig
- in hoe ‘n mate die spierverslappingsmedisyne jou nog affekteer.

Hoe **SUMABID** toegedien word

SUMABID sal deur jou narkotiseur aan jou toegedien word. Dit word as ‘n enkele inspuiting deur ‘n intraveneuse lyn toegedien.

Jou dokter sal jou inlig oor hoe lank jou behandeling met **SUMABID** sal duur.

As jy enige verdere vrae het oor die gebruik van hierdie medisyne, vra jou dokter of apteker.

As meer SUMABID aan jou toegedien word as wat aanbeveel word

Aangesien jou narkotiseur jou toestand noukeurig sal monitor, is dit onwaarskynlik dat jy te veel **SUMABID** sal ontvang. In die geval van oordosis, sal jou dokter egter die oordosis bestuur.

As jy enige verdere vrae het oor die gebruik van hierdie medisyne, vra jou narkotiseur of ander dokter.

As jy vergeet het om SUMABID te gebruik

Aangesien 'n gesondheidsorgverskaffer **SUMABID** sal toedien, is dit onwaarskynlik dat die

dosis oorgeslaan sal word.

As jy ophou om SUMABID te gebruik

As behandeling met **SUMABID** onderbreek word, sal herstel van jou spiere na 'n operasie dalk nie vinnig genoeg plaasvind om jou weer vroeër op jou eie te laat asemhaal nie

4. Moontlike newe-effekte

SUMABID kan newe-effekte hê.

Nie alle newe-effekte wat vir **SUMABID** aangemeld is, is in hierdie inligtingsblad ingesluit nie. Raadpleeg asseblief jou gesondheidsorgverskaffer vir advies indien jou algemene gesondheid sou versleg of as jy enige ongewenste effekte ervaar terwyl **SUMABID** aan jou toegedien word.

As hierdie newe-effekte voorkom terwyl jy onder narkose is, sal jou narkotiseur dit waarneem en jou behandel.

Ernstige newe-effekte

Indien enige van die volgende gebeur, lig jou dokter dadelik in of gaan na die noodgevalle-afdeling van jou naaste hospitaal:

Minder gereelde newe-effekte

- Allergiese (geneesmiddel-hipersensitiwiteit) reaksies - soos 'n uitslag, rooi vel, swelling van jou tong en/of keel, kortasemigheid, veranderinge in bloeddruk of hartklop, wat soms 'n ernstige afname in bloeddruk tot gevolg het. Erge allergiese of allergiese tipe-reaksies kan lewensgevaarlik wees. Allergiese reaksies is meer algemeen aangemeld by gesonde, bewuste vrywilligers.

Hierdie is almal baie ernstige newe-effekte. As jy bogenoemde gehad het, het jy dalk ‘n ernstige reaksie teen **SUMABID** gehad. Jy mag dringend mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

Minder gereelde newe-effekte

- Kortasemigheid as gevolg van spierkrampe van die lugweë (brongospasma) het voorgekom by pasiënte met 'n geskiedenis van longprobleme
- Erge verlangsaming van die hart en verlangsaming van die hart tot met hartstilstand kan voorkom wanneer **SUMABID** toegedien word

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Ander newe-effekte

Lig jou dokter so gou as moontlik in oor enige van die volgende newe-effekte:

Gereelde newe-effekte

- Hoes
- 'n Tydelike onaangename smaak in jou mond
- Lugwegprobleme wat hoes of beweging kan insluit asof jy wakker word of asemhaal
- Ligte narkose – jy kan dalk uit diepe slaap begin kom, dus het meer narkose nodig. Dit kan veroorsaak dat jy aan die einde van die operasie beweeg of hoes
- Komplikasies tydens jou prosedure soos veranderinge in hartklop, hoes of beweging
- Verlaagde bloeddruk as gevolg van die chirurgiese prosedure
- Jou spiere kan na die operasie langer verswak as wat verwag is.

Minder gereelde newe-effekte

- Terugkeer van spierverslapping na die operasie
- Wakker wees tydens die operasie (narkose-bewustheid).

Ander newe-effekte wat nie hierbo gelys is nie, kan by sommige pasiënte voorkom.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte

As jy newe-effekte ervaar, moet jy met jou dokter, apteker of verpleegkundige praat.

Jy kan ook newe-effekte by SAHPRA aanmeld *via* die SAHPRA Med Safety-toepassing (Medsafety X SAHPRA) en eReporting-platform (who-umc.org) wat aanlyn beskikbaar is op SAHPRA se webblad. Vermoedelike ongewenste effekte kan ook direk aan die houer van die registrasiesertifikaat aangemeld word *via* e-pos: pharmacovigilance.africasme@sunpharma.com of tel: +27(0) 12 643 2000.

Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **SUMABID** te verskaf.

5. Hoe om SUMABID te bewaar

Bewaar alle medisyne buite die bereik van kinders.

Oplossing vir inspuiting:

Bewaar by of onder 25°C.

Moenie gevries word nie.

Hou die flessie in die buitenste karton om dit teen lig te beskerm.

Verdunde oplossing vir inspuiting:

Bewaar by 2 °C tot 8 °C of onder 25 °C.

6. Inhoud van die verpakking en ander inligting

Wat SUMABID bevat

Die aktiewe bestanddeel is sugammadex.

Die ander bestanddele is:

Water vir Inspuiting

Soutsuur of natriumhidroksied

Stikstof

Hoe SUMABID lyk en inhoud van die verpakking

SUMABID word verpak in tipe I glasflessies met ‘n bromobutiel-rubberprop. ‘n Aluminiumdoppie met ‘n aftrekbare seël word op die flessie aangebring. Die aluminiumdop word aangebring om die rubberprop styf aan die glasflessie vas te maak.

Verpakkingsgrootte: 10 flessies van 2 mL verpak in 'n kartonhouer.

Houer van die Registrasiesertifikaat

RANBAXY PHARMACEUTICALS (PTY) LTD

‘n Sun Pharma maatskappy

Lautreweg 14, Stormill, Uitbreiding 1,

Roodepoort, 1724

Suid-Afrika

Tel: +27(0) 12 643 2000

Hierdie inligtingstuk was laas hersien op:

16 Julie 2026

Registrasienommer

56/34/0244

Slegs Namibië: NS2

SUMABID 100 IV: 04/20.1.1/0602

Toegang tot die ooreenstemmende vertaling van die PIL:

Die PIL is beskikbaar in een ander taal (Afrikaans), ‘n afskrif is toeganklik op die firma se

webtuiste: https://sunpharma.com/south-africa-products/