PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CIAVOR 5 – 5mg Film coated tablets

Tadalafil

Contains Lactose

Read all of this leaflet carefully before you start taking CIAVOR 5

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

1. What CIAVOR is and what it is used for

CIAVOR is a treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. CIAVOR has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

CIAVOR contains the active substance tadalafil which belongs to a group of medicines called Phosphodiesterase type 5 inhibitors. Following sexual stimulation CIAVOR works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function. CIAVOR will not help you if you do not have erectile dysfunction.

It is important to note that CIAVOR does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

2. What you need to know before you take CIAVOR

Do not take CIAVOR if you:

- are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6).
- are taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines ("nitrates") used in the treatment of angina pectoris ("chest pain"). CIAVOR has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor.
- have serious heart disease or recently had a heart attack within the last 90 days.
- recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.
- have a severe hepatic (liver) insufficiency (Child-Pugh Class C).
- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "stroke of the eye".
- if you have had previously experienced of a decrease or loss of hearing in one or both ears, with or without dizziness.

Warnings and precautions

Talk to your doctor before taking CIAVOR.

Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart. If you have a heart problem you should tell your doctor.

Before taking the tablets, tell your doctor if you have:

- sickle cell anaemia (an abnormality of red blood cells).
- multiple myeloma (cancer of the bone marrow).
- leukaemia (cancer of the blood cells).
- any deformation of your penis.
- a serious liver problem.
- a severe kidney problem.

It is not known if CIAVOR is effective in patients who have had:

- pelvic surgery.
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical nonnerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision, stop taking CIAVOR and contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking CIAVOR and contact your doctor immediately.

CIAVOR is not intended for use by women.

Children and adolescents

CIAVOR is not intended for use by children and adolescents under the age of 18.

Other medicines and CIAVOR

Tell your doctor if you are taking, have recently taken or might take any other medicines

Do not take CIAVOR if you are already taking nitrates.

Some medicines may be affected by CIAVOR or they may affect how well CIAVOR will work.

Tell your doctor or pharmacist if you are already taking:

- an alpha blocker (used to treat high blood pressure or urinary symptoms associated with benign prostatic hyperplasia).
- other medicines to treat high blood pressure.
- a 5- alpha reductase inhibitor (used to treat benign prostatic hyperplasia).
- medicines such as ketoconazole tablets (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

CIAVOR with drink and alcohol

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well CIAVOR will work and should be taken with caution. Talk to your doctor for further information.

Driving and using machines

Some men taking CIAVOR in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

CIAVOR contains lactose

If you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take CIAVOR

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

CIAVOR tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

The recommended dose is one 5 mg tablet taken once a day at approximately the same time of the day.

Do not take CIAVOR more than once a day.

Once a day dosing of CIAVOR may be useful to men who anticipate having sexual activity two or more times per week.

When taken once a day CIAVOR allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day.

It is important to note that CIAVOR does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take CIAVOR, avoid excessive drinking (blood alcohol level of 0.08 % or greater), since this may increase the risk of dizziness when standing up.

If you take more CIAVOR than you should

Contact your doctor. You may experience side effects described in section 4.

If you forget to take CIAVOR

Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet. You should not take CIAVOR more than once a day.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

These effects are normally mild to moderate in nature.

If you experience any of the following side effects stop using the medicine and seek medical help immediately:

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon).
- priapsim, a prolonged and possibly painful erection after taking CIAVOR (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision (frequency rare).

Other side effects have been reported:

Common (seen in 1 to 10 in every 100 patients)

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion and indigestion.

Uncommon (seen in 1 to 10 in every 1,000 patients)

- dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding heartbeat

sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired.

Rare (seen in 1 to 10 in every 10,000 patients)

- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating.

Heart attack and stroke have also been reported rarely in men taking CIAVOR. Most of these men had known heart problems before taking this medicine.

Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Some additional rare side effects have been reported in men taking CIAVOR that were not seen in clinical trials. These include:

- migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death.

The side effect dizziness has been reported more frequently in men over 75 years of age taking CIAVOR. Diarrhoea has been reported more frequently in men over 65 years of age taking CIAVOR.

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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction 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 CIAVOR.

5. How to store CIAVOR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What CIAVOR contains

- The active substance is tadalafil. Each tablet contains 5 mg of tadalafil.
- The other ingredients are:

  Tablet core: lactose monohydrate (see end of section 2), croscarmellose sodium, hydroxypropylcellulose, microcrystalline cellulose, sodium laurilsulfate, magnesium stearate.

  Film-coat: lactose monohydrate, hypromellose, triacetin, titanium dioxide (E171), iron oxide yellow (E172), talc.

What CIAVOR looks like and contents of the pack

CIAVOR 5 is a light yellow film-coated tablet in the shape of an almond and has "C 5" marked on one side.

CIAVOR 5 is available in blister packs containing 14 or 28 tablets.

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

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Registration number

48/7.1.5/0657

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS: S4

CIAVOR 5 – 5 mg Filmbedekte tablette

Tadalafiel

Bevat Laktose

Lees hierdie hele pamflet sorgvuldig deur voordat jy CIAVOR 5 begin neem

- Bewaar hierdie pamflet. Jy sal dit dalk later weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- CIAVOR 5 is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander mense deel nie. Dit kan skadelik wees vir hulle, selfs indien hulle simptome dieselfde as jou simptome is.

Wat in hierdie pamflet is

1. Wat CIAVOR 5 is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy CIAVOR 5 neem
3. Hoe om CIAVOR 5 te neem
4. Moontlike newe-effekte
5. Hoe om CIAVOR 5 te bewaar
6. Inhoud van die pak en ander inligting

1. Wat CIAVOR 5 is en waarvoor dit gebruik word

CIAVOR 5 is ʼn behandeling vir volwasse mans met erektiele disfunksie. Dit is wanneer ʼn man se penis nie styf genoeg kan word of bly sodat dit geskik is vir seksuele aktiwiteit nie. Daar is aangetoon dat CIAVOR 5 ʼn man se vermoë aansienlik verbeter om ʼn stywe, opgehewe penis te verkry wat geskik is vir seksuele aktiwiteit.

CIAVOR 5 bevat die aktiewe stof tadalafiel wat behoort tot ʼn groep medisyne genaamd Fosfodiësterase tipe 5-inhibeerders. Ná seksuele stimulering werk CIAVOR 5 deur die bloedvate in jou penis te help ontspan, sodat bloed na jou penis kan vloei. Die gevolg hiervan is verbeterde erektiele funksie. CIAVOR 5 sal jou op geen manier help indien jy nie erektiele disfunksie het nie. Dit is belangrik om daarop te let dat CIAVOR 5 nie werk as daar geen seksuele stimulering is nie. Dit is steeds nodig vir vóórspel tussen jou en jou seksmaat, net soos wat dit nodig sou wees indien jy nie medisyne vir erektiele disfunksie gebruik het nie.

2. Wat jy moet weet voordat jy CIAVOR 5 neem

Moenie CIAVOR 5 neem nie indien jy:

- allergies is vir tadalafiel of enige van die ander bestanddele van hierdie medisyne (gelys in afdeling 6).
- enige vorm van organiese nitraat of stikstofmonoksied-donors soos amielnitriet neem. Dit is ʼn groep medisyne (“nitrate”) wat gebruik word vir die behandeling van angina pectoris (“borskaspyn”). Daar is aangetoon dat CIAVOR 5 die effekte van hierdie medisyne versterk. Indien jy enige vorm van nitraat neem of onseker is, vertel vir jou dokter.
- ernstige hartsiekte het of onlangs, in die afgelope 90 dae, ʼn hartaanval gehad het.
- onlangs, in die afgelope 6 maande, ʼn beroerte gehad het.
- lae bloeddruk of ongekontroleerde hoë bloeddruk het.
- ernstige hepatiese (lewer-) ontoereikendheid het (Child-Pugh Klas C).
- al ooit sigverlies gehad het weens nie-arteritiese anterior iskemiese optiese neuropatie (NAION), ʼn toestand wat beskryf word as ʼn “oogberoerte”.

- al vantevore verswakte gehoor of gehoorverlies in een of albei ore ondervind het, met of sonder gepaardgaande duiseligheid.

Waarskuwings en voorsorgmaatreëls

Praat met jou dokter voordat jy CIAVOR 5 neem.

Hou in gedagte dat seksuele aktiwiteit ’n moontlike risiko vir pasiënte met hartsiekte inhou aangesien dit ekstra inspanning vir jou hart meebring. Indien jy ’n hartprobleem het, moet jy jou dokter daarvan vertel.

Voordat jy die tablette neem, vertel vir jou dokter indien jy enige van die volgende probleme het:

- sekelselanemie (’n abnormaliteit van rooibloedselle).
- veelvuldige miëloom (kanker van die beenmurg).
- leukemie (kanker van die bloedselle).
- enige misvorming van jou penis.
- ’n ernstige lewerprobleem.
- ’n ernstige nierprobleem.

Dit is nie bekend of CIAVOR 5 effektief is in pasiënte wat enige van die volgende ondergaan het nie:

- bekkenchirurgie.
- die algehele of gedeeltelike verwydering van die prostaatklier waartydens senuwees van die prostaat afgesny word (radikale niesenuweesparende prostatektomie).

Indien jy skielik verswakte sig of sigverlies ervaar, moet jy ophou om CIAVOR 5 te neem en onmiddellik jou dokter raadpleeg.

Verswakte gehoor of skielike gehoorverlies is al waargeneem in sommige pasiënte wat tadalafiel neem. Alhoewel dit nie bekend is of hierdie gebeure direk aan tadalafiel toegeskryf

kan word nie, moet jy ophou om CIAVOR 5 te neem en onmiddellik jou dokter raadpleeg indien jy verswakte gehoor of skielike gehoorverlies ervaar.

CIAVOR 5 is nie bedoel om deur vroue gebruik te word nie.

Kinders en adolessente

CIAVOR 5 is nie bedoel om deur kinders en adolessente jonger as 18 jaar gebruik te word nie.

Ander medisyne en CIAVOR 5

Vertel vir jou dokter indien jy enige ander medisyne neem, onlangs geneem het, of moontlik in die toekoms gaan neem.

Moenie CIAVOR 5 neem indien jy reeds nitrate neem nie.

Sommige medisyne kan moontlik geaffekteer word deur CIAVOR 5, of kan die werking van CIAVOR 5 beïnvloed. Vertel vir jou dokter of apteker indien jy reeds enige van die volgende neem:

- ŉ alfablokker (vir die behandeling van hoë bloeddruk of urinêre simptome geassosieer met nie kwaadaardige prostaathiperplasie).
- ander medisyne vir die behandeling van hoë bloeddruk.
- ŉ 5-alfa-reduktase-inhibeerder (vir die behandeling van nie kwaadaardige prostaathiperplasie).
- medisyne soos ketokonasooltablette (vir die behandeling van swaminfeksies) en protease-inhibeerders vir die behandeling van VIGS of MIV-infeksie.
- fenobarbitoon, fenitoïen en karbaamasepien (antikonvulsante).
- rifampisien, eritromisien, klaritromisien of itrakonasool.
- ander behandelings vir erektiele disfunksie.

CIAVOR 5 saam met drank en alkohol

Inligting oor die effek van alkohol is in afdeling 3. Pomelosap kan die doeltreffendheid van CIAVOR 5 beïnvloed en moet met omsigtigheid geneem word. Praat met jou dokter vir verdere inligting.

Bestuur en die gebruik van masjinerie

ʼn Aantal mans wat CIAVOR 5 in kliniese studies geneem het, het duiseligheid as newe-effek aangemeld. Kyk eers noukeurig hoe jy op die tablette reageer voordat jy ʼn motor bestuur of masjinerie gebruik.

CIAVOR 5 bevat laktose

Indien jy ʼn onverdraagsaamheid vir sekere suikers het, raadpleeg jou dokter voordat jy hierdie medisyne neem.

3. Hoe om CIAVOR 5 te neem

Neem hierdie medisyne altyd presies volgens jou dokter se instruksies. Raadpleeg jou dokter of apteker indien jy onseker is.

CIAVOR 5-tablette is slegs vir mondelikse gebruik deur mans. Sluk die tablet heel af met water.

Die tablette kan met of sonder voedsel geneem word.

Die aanbevole dosis is één 5 mg-tablet wat een maal per dag op ongeveer dieselfde tyd van die dag geneem word.

Moenie CIAVOR 5 meer as een maal per dag neem nie.

Een dosis van CIAVOR 5 per dag kan raadsaam wees vir mans wat verwag dat hulle twee of meer kere per week seksueel aktief gaan wees.

Indien CIAVOR 5 een maal per dag geneem word, maak dit ʼn ereksie moontlik wanneer jy seksueel gestimuleer word op enige tydstip gedurende die 24 ure van die dag.

Dit is belangrik om daarop te let dat CIAVOR 5 nie werk as daar geen seksuele stimulering is nie. Dit is steeds nodig vir vóórspel tussen jou en jou seksmaat, net soos wat dit nodig sou wees indien jy nie medisyne vir erektiele disfunksie gebruik het nie.

Alkoholgebruik kan jou vermoë beïnvloed om ’n ereksie te kry en kan jou bloeddruk tydelik verlaag. Indien jy CIAVOR 5 geneem het of beplan om dit te neem, moet jy oormatige inname van alkohol vermy (bloedalkoholvlak van 0,08 % of meer), aangesien dit die risiko vir duiseligheid verhoog wanneer jy vanuit ’n sittende of lêende posisie opstaan.

Indien jy meer CIAVOR 5 neem as wat jy moet

Raadpleeg jou dokter. Jy sal moontlik newe-effekte ervaar soos beskryf in afdeling 4.

Indien jy vergeet om CIAVOR 5 te neem

Neem jou dosis sodra jy daarvan onthou, maar moenie ’n dubbele dosis neem om op te maak vir ’n vergete tablet nie. Moenie CIAVOR 5 meer as een maal per dag neem nie.

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

4. Moontlike newe-effekte

Soos wat met alle medisyne die geval is, kan hierdie medisyne ook newe-effekte tot gevolg hê, maar nie alle mense word daardeur beïnvloed nie. Hierdie effekte is gewoonlik matig tot matig ernstig van aard.

Indien jy enige van die volgende newe-effekte ervaar, staak die gebruik van die medisyne en kry onmiddellik mediese hulp:

- allergiese reaksies insluitende uitslae (frekwensie nie-algemeen).
- borskaspyn – moenie nitrate gebruik nie, maar kry onmiddellik mediese hulp (frekwensie nie-algemeen).

- priapisme, ’n langdurige en moontlik pynlike ereksie nadat jy CIAVOR 5 geneem het (frekwensie seldsaam). Indien jy so ’n ereksie het wat vir langer as 4 ure aanhou, moet jy ’n dokter onmiddellik daaroor raadpleeg.
- skielike sigverlies (frekwensie seldsaam).

Ander newe-effekte is ook al aangemeld:

Algemeen (kom voor by 1 tot 10 uit elke 100 pasiënte)

- hoofpyn, rugpyn, spierpyne, pyn in arms en bene, gesigsblosing, neuskongestie en slegte spysvertering.

Nie-algemeen (kom voor by 1 tot 10 uit elke 1 000 pasiënte)

- duiseligheid, maagpyn, naarheid, braking, refluks, dowwe visie, oogpyn, probleme met asemhaling, teenwoordigheid van bloed in urine, langdurige ereksie, hamerende hartklop-sensasie, ’n vinnige harttempo, hoë bloeddruk, lae bloeddruk, neusbloeding, gesuis in die ore, swelling van die hande, voete of enkels, en moegheid.

Seldsaam (kom voor by 1 tot 10 uit elke 10 000 pasiënte)

- floute, toevalle en tydelike geheueverlies, swelling van die ooglede, rooi oë, skielike verswakte gehoor of gehoorverlies, galbulte (jeukerige rooi bulte op die veloppervlak), bloeding vanuit die penis, teenwoordigheid van bloed in semen, en toename in sweet.
- Hartaanval en beroerte is ook in enkele seldsame gevalle aangemeld in mans wat CIAVOR 5 neem. Die meeste van hierdie mans het bekende hartprobleme gehad voordat hulle hierdie medisyne geneem het.
- Gedeeltelike, tydelike, of permanente verswakte sig of sigverlies in een of albei oë is in seldsame gevalle aangemeld.

'n Aantal bykomende seldsame newe-effekte is al aangemeld in mans wat CIAVOR 5 neem wat nie in kliniese proewe waargeneem is nie. Dit sluit in:

- migraine, swelling van die gesig, ernstige allergiese reaksie wat swelling van die gesig of keel veroorsaak, ernstige veluitslae, versteurings wat bloedvloei na die oë beïnvloed, onreëlmatige hartklop, angina en skielike hartstilstand.

Die newe-effek duiseligheid is meer dikwels aangemeld in mans ouer as 75 jaar wat CIAVOR 5 neem. Diarree is meer dikwels aangemeld in mans ouer as 65 jaar wat CIAVOR 5 neem.
Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet vermeld word nie, stel asseblief jou dokter of apteker daarvan in kennis.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, raadpleeg jou dokter of apteker. Jy kan ook newe-effekte aanmeld by SAHPRA via die **"6.04 Adverse Drug Reaction Form"**, aanlyn beskikbaar onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van CIAVOR 5 te verskaf.

5. Hoe om CIAVOR 5 te bewaar

Hou hierdie medisyne buite die sig en bereik van kinders.
Moenie hierdie medisyne gebruik ná die vervaldatum wat op die kartonhouer en stolpstrokie ná 'EXP' aangedui is nie. Die vervaldatum verwys na die laaste dag van die betrokke maand.
Bewaar in die oorspronklike verpakking om teen vog te beskerm. Moenie bokant 25 °C bewaar nie.
Medisynes moenie via afvalwater of huishoudelik afval weggegooi word nie. Vra jou apteker hoe om ontslae te raak van medisyne wat jy nie meer gebruik nie. Hierdie maatreëls sal help om die omgewing te beskerm.

6. Inhoud van die verpakking en ander inligting

Wat CIAVOR 5 bevat

- Die aktiewe middel is tadalafiel. Elke tablet bevat 5 mg tadalafiel.
- Die ander bestanddele is:

  Tabletkern: laktosemonohidraat (sien einde van afdeling 2), kroskarmellose natrium, hidroksipropielsellulose, mikrokristallyne sellulose, natriumlourielsulfaat, magnesiumstearaat.

  Filmdeklaag: laktosemonohidraat, hipromellose, triasetien, titaandioksied (E171), geel ysteroksied (E172), talk.

Hoe CIAVOR 5 lyk en inhoud van die verpakking

CIAVOR 5 is ŉ liggeel filmbedekte tablet in die vorm van ŉ amandel, gemerk met “C 5” aan die een kant.

CIAVOR 5 is beskikbaar in stolpstrokies wat 14 of 28 tablette bevat.

Alle pakgroottes word nie noodwendig bemark nie.

Houer van Registrasiesertifikaat

Eli Lilly (S.A.) (Pty) Ltd

Eerste Verdieping, Golden Oak House, Ballyoaks Office Park,

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RSA.

Hierdie pamflet is laas hersien op 05 Mei 2022.

Registrasienommer

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