

Applicant/PHCR: Innovata Pharmaceuticals Pty. Ltd.
Product Proprietary Name: SEPTAPEN 250
Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
Registration date: 8 February 1999

CTD, Module 1

SCHEDULING STATUS:

S4

SEPTAPEN 250 capsules

Flucloxacillin sodium

Sugar free

Read all of this leaflet carefully before you start taking SEPTAPEN 250.

- 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.
- **SEPTAPEN 250** 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 **SEPTAPEN 250** is and what it is used for
2. What you need to know before you take **SEPTAPEN 250**
3. How to take **SEPTAPEN 250**
4. Possible side effects
5. How to store **SEPTAPEN 250**
6. Contents of the pack and other information

1. WHAT SEPTAPEN 250 is and what it is used for:

SEPTAPEN 250 contains the active substance called floxacillin. Flucloxacillin belongs to a class of antibiotics called “penicillinase-resistant penicillins” and is used to treat bacterial infections including:

- Skin and soft tissue infections
- Respiratory tract infections
- Other infections
 - Osteomyelitis (affecting the bone and bone marrow)
 - Enteritis (affecting the intestinal tract, especially the small intestine)
 - Endocarditis (inflammation of the lining of the heart and its valves),
 - Kidney, bladder, or urethra (the tube which carries urine from the bladder)
 - Meningitis (a serious disease characterised by inflammation of the membranes around the brain or spinal cord)
 - Septicaemia (blood poisoning)
 - Otitis Media (infection of the ear)
 - Wounds and burn wounds.

2. What you need to know before you take SEPTAPEN 250

Do not take SEPTAPEN 250:

- If you are hypersensitive (allergic) to penicillins/flucloxacillin sodium or any of the other ingredients of **SEPTAPEN 250** (listed in section 6).
- If you have had an allergic reaction to β -lactam antibiotics (e.g. penicillins, cephalosporins).

Applicant/PHCR: Innovata Pharmaceuticals Pty. Ltd.
Product Proprietary Name: SEPTAPEN 250
Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
Registration date: 8 February 1999

CTD, Module 1

- If you have a previous history of flucloxacillin associated jaundice or hepatic dysfunction.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- If you have kidney problems, as you may require a lower dose than normal (convulsions may occur very rarely in patients with kidney problems who take high doses).
- if you are taking or will be taking paracetamol
- if you are taking this medicine for a long time as regular tests of liver and kidney function are advised
- if you suffer from liver problems, as this medicine could cause them to worsen.

Tests

Regular monitoring kidney function should be performed whilst taking SEPTAPEN 250 for a long period of time. Tell your doctor that you are taking SEPTAPEN 250 if you are having urine tests or blood tests because it may affect the results.

Use in children and adolescents

SEPTAPEN 250 must not be given to children. Safety and efficacy has not been established.

Other medicines and SEPTAPEN 250

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

Tell your health care provider if you are taking any of the following:

- probenecid or sulfinpyrazone (used in the treatment of gout)
- piperacillin (an antibiotic taken by injection)
- methotrexate (a chemotherapy medicine)
- oral typhoid vaccine (antibiotics can make this less effective)
- sugammadex (used in general anaesthetics)
- warfarin (medicine to prevent blood clotting)
- paracetamol
- Voriconazole (used to treat fungal infection- flucloxacillin can reduce levels of this medicine in your body)

SEPTAPEN 250 with food and drink

Take **SEPTAPEN 250** capsules half an hour to one (1) hour before meals.

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 health care provider for advice before taking **SEPTAPEN 250**.

Driving and using machines

SEPTAPEN 250 are not expected to affect your ability to drive or operate machinery.

It is not always possible to predict to what extent **SEPTAPEN 250** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the

above activities until they are aware of the measure to which **SEPTAPEN 250** affects them.

3. How to take SEPTAPEN 250

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

Always take **SEPTAPEN 250** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

For oral use only.

Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food. It is important that you take your medicine at the right times.

The dose will depend on the patient and will be decided by your doctor.

Adults

Take one (1) capsule four (4) times a day, your doctor may prescribe a different dose for severe infections.

- Joint infections (osteomyelitis) or heart infections (endocarditis) up to 8 g daily in divided doses, six to eight hourly.

Kidney problems:

The dose may need to be reduced; your doctor will prescribe a suitable dose for you.

If you take more SEPTAPEN 250 than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take SEPTAPEN 250

Date of PI: 09/05/2024

Applicant/PHCR: *Innovata Pharmaceuticals Pty. Ltd.*
Product Proprietary Name: SEPTAPEN 250
Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
Registration date: 8 February 1999

CTD, Module 1

If you miss a dose, take it as soon as you remember and carry on as before.

If it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

If you stop taking SEPTAPEN 250

Do not stop taking **SEPTAPEN 250** because some bacteria may survive and cause the infection to come back. Do not stop taking **SEPTAPEN 250** without first talking to your doctor.

4. POSSIBLE SIDE EFFECTS

SEPTAPEN 250 can have side effects.

Not all side effects reported for **SEPTAPEN 250** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SEPTAPEN 250**, please consult your health care provider for advice.

If any of the following happens, stop taking **SEPTAPEN 250** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction, symptoms of which includes rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue.
- severe bloody diarrhoea (pseudomembranous colitis)
- jaundice (yellow colour in the skin and whites of the eyes), hepatitis (liver inflammation) - sometimes these effects on the liver can be delayed for up to 2 months after finishing treatment.
- severe skin rash with flushing, fever, blisters, or ulcers (Stevens - Johnson syndrome)

Applicant/PHCR: Innovata Pharmaceuticals Pty. Ltd.
Product Proprietary Name: SEPTAPEN 250
Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
Registration date: 8 February 1999

CTD, Module 1

- severe rash with reddening, peeling, and swelling of the skin that looks like a burn (toxic epidermal necrolysis).
- changes in numbers of blood cells (causing unexplained bleeding, bruising or skin discolouration).

These are very serious side effects. If you have them, you may have had a serious reaction to **SEPTAPEN 250**. 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:

- difficulty breathing
- less urine than is normal for you.
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:

Frequent:

- Diarrhoea, nausea & vomiting

Less frequent:

- Urticaria (itchy skin eruption)
- Purpura (brownish-red spots on the skin)
- Inflammation of the kidney
- Blood abnormalities i.e. neutropenia and thrombocytopenia, eosinophilia, haemolytic anaemia

Applicant/PHCR: Innovata Pharmaceuticals Pty. Ltd.
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Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
Registration date: 8 February 1999

CTD, Module 1

- Anaphylactic Shock (severe allergic reaction)
- Angioneurotic Oedema (rapid swelling)
- Pseudomembranous colitis (type of inflammation of the colon)
- Changes in liver function tests
- Erythema multiforme (a red rash caused by hypersensitivity to a drug or disease or other allergen),
- Arthralgia (pain in a joint) and myalgia (pain in the muscles).
- Interstitial nephritis (Nephritis in which the interstitial connective tissue is chiefly affected)
- Very rare cases of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, generally in the presence of risk factors (see section 2).

Some of these reactions can be delayed for up to two months after finishing the treatment.

Frequency not known:

- Serious skin reaction - A red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).

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 Reporting Form”, found

Date of PI: 09/05/2024

Applicant/PHCR: *Innovata Pharmaceuticals Pty. Ltd.*
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Registration date: *8 February 1999*

CTD, Module 1

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 **SEPTAPEN 250**.

5. HOW TO STORE SEPTAPEN 250

Store all medicines out of reach of children.

Store at or below 25 °C, in dry place

Store in the original packaging.

Do not use the capsules after the expiry date stated on the label.

Do not store in the bathroom.

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 SEPTAPEN 250 contains

The active substance is flucloxacillin sodium.

The other ingredients are:

Magnesium stearate.

Size 2 black/red hard gelatine capsule components:

Black oxide, erythrosine, gelatine, red oxide, titanium dioxide

What SEPTAPEN 250 looks like and contents of the pack

SEPTAPEN 250 capsules are black/red size "2" hard gelatine capsules.

Date of PI: 09/05/2024

Applicant/PHCR: Innovata Pharmaceuticals Pty. Ltd.
Product Proprietary Name: SEPTAPEN 250
Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
Registration date: 8 February 1999

CTD, Module 1

SEPTAPEN 250 is available in:

Amber glass bottles containing 20 or 100 capsules.

20's, 100's and 40's printed Alu/LDPE patient ready packs.

PP/HDPE securitainers containing 20 or 100 capsules.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Innovata Pharmaceuticals (Pty) Ltd

Crownwood Office Park,

Block D, Ground floor

100 Northern Parkway

Ormonde

Johannesburg

2091

This leaflet was last revised in

09/05/2024

REGISTRATION NUMBER

A 29/20.1.2/0550

Access to the corresponding Professional information.

Follow the link for the corresponding Professional Information for **SEPTAPEN**:

pi-pil-repository.innovata.co.za,

alternatively please scan the QR code below:

Date of PI: 09/05/2024

Applicant/PHCR: *Innovata Pharmaceuticals Pty. Ltd.*
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CTD, Module 1



SKEDULERINGSSTATUS:

S4

SEPTAPEN 250 kapsules

Flukloksasillien natrium

Suikervry

Lees die volledige biljet noukeurig deur voordat u begin om SEPTAPEN 250 te neem.

- Hou hierdie biljet. U mag dit moontlik weer wil lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgvoorsiener.
- **SEPTAPEN 250** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit kan hulle kwaad aandoen, selfs indien hulle simptome dieselfde is as diè wat u het.

Wat is in hierdie biljet

1. Wat is **SEPTAPEN 250** en waarvoor dit gebruik word
2. Wat u behoort te weet voordat u **SEPTAPEN 250** neem
3. Hoe om **SEPTAPEN 250** te neem
4. Moontlike newe-effekte
5. Hoe om **SEPTAPEN 250** te berg
6. Inhoud van die pakkie en ander inligting

1. WAT SEPTAPEN 250 IS EN WAARVOOR DIT GEBRUIK WORD:

SEPTAPEN 250 bevat die aktiewe bestanddeel wat genoem word flukloksasillien. Flukloksasillien behoort aan 'n klas van antibiotika wat genoem word "penisillinase-weerstandige penisilliene" en word gebruik by behandeling van bakteriële infeksies insluitend:

- Vel- en sagte weefselinfeksies
- Respiratoriese lugweginfeksies
- Ander infeksies
 - Osteomiëlitis (beïnvloed die been en beenmurg)
 - Enteritis (beïnvloed die intestinale weg, veral die dunderm)
 - Endokarditis (inflammasie van die belyning van die hart en sy kleppe)
 - Nier, blaas of uretra (die buis wat die uriene neem vanaf die blaas)
 - Meningitis ('n ernstige siekte gekenmerk deur inflammasie van die membrane rondom die brein of spinale koord)
 - Septisemie (bloed-vergiftiging)
 - Otitis Media (infeksie van die oor)
 - Wonde en brandwonde.

2. Wat u behoort te weet voordat u SEPTAPEN 250 neem

Moenie SEPTAPEN 250 neem:

- Indien u hipersensitief (allergies) is vir penisilliene/flukloksasillien natrium of enige van die ander bestanddele van **SEPTAPEN 250** nie (aangedui in afdeling 6).

- Indien u ooit 'n allergiese reaksie gehad het met β -laktam antibiotika (bv. penisilliene, kefalosporiene).
- Indien u 'n vorige geskiedenis het van flukloksasillien geassosieerde geelsug of hepatiese disfunksie.

Waarskuwings en voorsorgmaatreëls

Raadpleeg u dokter of apteker voordat u die medisyne neem:

- Indien u nierprobleme het, omdat u 'n laer dosis as normaal kan benodig (konvulsies kan soms voorkom by pasiënte met nierprobleme wat hoë doserings geneem het)
- indien u parasetamol neem of beplan om dit te neem
- indien u hierdie medisyne vir 'n lang tyd neem omdat gereëelde toetse van lewer- en nierfunksie aanbeveel word
- indien u nierprobleme het, omdat hierdie medisyne kan veroorsaak dat dit agteruitgaan.

Toetse

Gereëelde monitering van nierfunksie moet gedoen word terwyl u **SEPTAPEN 250** vir 'n lang tydperk neem. Vertel u dokter dat u **SEPTAPEN 250** neem indien u uriene toetse of bloedtoetse laat doen omdat dit die resultate kan beïnvloed.

Gebruik in kinders en adolessente

SEPTAPEN 250 moet nie aan kinders gegee word nie. Veiligheid en effektiwiteit is nog nie vasgestel nie.

Ander medisyne en SEPTAPEN 250

Vertel altyd u gesondheidsorgvoorsiener indien u enige ander medisyne neem. (Dit sluit alle komplementere of tradisionele medisyne in.)

Vertel u gesondheidsorgvoorsiener indien u enige van die volgende neem:

- probenesied of sulfienpirasoon (word gebruik by die behandeling van jig)
- piperasillien ('n antibiotikum toegedien deur 'n inspuiting)
- metotreksaat ('n chemoterapeutiese medisyne)
- orale tifoïed vaksiene (antibiotika kan dit minder effektief maak)
- sugammadeks (word gebruik by algemene narkose)
- warfarien (medisyne vir voorkoming van bloedklonte)
- parasetamol
- vorikonasool (word gebruik by behandeling van fungusinfeksies -
flukloksasillien kan die vlakke van hierdie medisyne laat afneem in u liggaam)

SEPTAPEN 250 met voedsel en drankies

Neem **SEPTAPEN 250** kapsules 'n halfuur tot een (1) voor u maaltye.

Swangerskap en borsvoeding

Indien u swanger is of borsvoed, dink dat u swanger kan wees of 'n baba beplan, raadpleeg u dokter, apteker of ander gesondheidsorgvoorsiener vir advies voordat u **SEPTAPEN 250** neem.

Bestuur en gebruik van masjinerie

SEPTAPEN 250 word nie verwag om u vermoë om te bestuur of masjinerie te hanteer te beïnvloed nie.

Dit is nie altyd moontlik om te voorspel tot watter mate **SEPTAPEN 250** kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet seker maak dat hulle nie deelneem aan die bogemelde aktiwiteite nie totdat hulle seker is tot watter mate **SEPTAPEN 250** hulle beïnvloed.

3. Hoe om **SEPTAPEN 250** te neem

Moenie medisyne wat vir u voorgeskryf is met ander mense deel nie.

Neem **SEPTAPEN 250** altyd presies soos u dokter u aanbeveel het. U moet u dokter of apteker raadpleeg indien u nie seker is nie.

Slegs vir orale gebruik.

Neem hierdie medisyne wanneer u maag leeg is. Dit beteken 'n uur voor inname van voedsel of 2 uur na voedsel. Dit is belangrik dat u hierdie medisyne op die regte tye neem.

Die dosis sal afhang van die pasiënt en sal deur u dokter bepaal word.

Volwassenes

Neem een (1) kapsule vier (4) keer per dag, u dokter kan 'n verskillende dosis voorskryf vir ernstige infeksies.

- Gewrigsinfeksies (osteomiëlitis) of hartinfeksies (endokarditis) op tot 8 g per dag in verdeelde doserings, ses tot agt uurliks.

Nierprobleme:

Applicant/PHCR: Innovata Pharmaceuticals Pty. Ltd.
Product Proprietary Name: SEPTAPEN 250
Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
Registration date: 8 February 1999

CTD, Module 1

Dit kan moontlik nodig wees om die dosis te verminder; u dokter sal 'n geskikte dosis vir u voorskryf.

Indien u meer SEPTAPEN 250 geneem het as wat u moes

Ingeval van oordosering, raadpleeg u dokter of apteker. Indien albei nie beskikbaar is nie, kontak die naaste hospitaal of vergiftingsentrum.

Indien u vergeet het om SEPTAPEN 250 te neem

Indien u dosis mis, neem dit so gou as wat u onthou en gaan dan aan soos voorheen.

Indien dit amper tyd is vir u volgende dosis, slaan die dosis oor wat u gemis het en gaan voort soos gewoonlik. Moenie 'n dubbel dosis neem om op te maak vir die dosis wat u vergeet het nie.

Indien u die neem van SEPTAPEN 250 staak

Moenie die neem van **SEPTAPEN 250** staak nie omdat sommige bakterieë kan oorleef en veroorsaak dat die infeksie weer terugkeer. Moenie die neem van **SEPTAPEN 250** stop sonder om eers met u dokter te praat nie.

4. NEWE-EFFEKTE

SEPTAPEN 250 kan newe-effekte veroorsaak.

Nie alle newe-effekte gerapporteer vir **SEPTAPEN 250** is ingesluit in hierdie biljet nie. Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ondervind terwyl u **SEPTAPEN 250** neem, raadpleeg asseblief u gesondheidsorgvoorsiener vir advies.



Indien enige van die volgende gebeur, staak die gebruik van **SEPTAPEN 250** en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal.

- 'n allergiese reaksie, simptome wat kan insluit uitslag, jeuk, probleme met asemhaling of opswel van die gesig, lippe, keel of tong.
- ernstige bloederige diarree (pseudomembraneuse kolitis)
- geelsug (geel kleur van die vel en wit van die oë), hepatitis (lewer-inflammasie) - soms kan hierdie effekte op die lewer vertraag word vir tot 2 maande nadat behandeling voltooi is.
- ernstige veluitslag met blosing, koors, blasies of ulkuse (Stevens - Johnson se sindroom).
- ernstige uitslag met rooierigheid, afdop en opswel van die vel wat lyk soos 'n brand (toksiese epidermale nekrolise).
- veranderinge in hoeveelheid van bloedselle (wat onverklaarbare bloeding veroorsaak, kneusing of toksiese verkleuring).

Hierdie is baie ernstige newe-effekte. Indien u dit het, het u moontlik 'n baie ernstige reaksie gehad met **SEPTAPEN 250**. U mag dringende mediese sorg of hospitalisering benodig.

Vertel u dokter onmiddelik of gaan na die ongevalle departement by u naaste hospitaal indien u enige van die volgende opmerk:

- asemhaling probleme.
- minder uriene as wat normaal is vir u.
- geel word van die vel en oë, donker uriene en moegheid, wat simptome kan wees van lewerprobleme.

Hierdie is almal ernstige newe-effekte. U kan moontlik dringende mediese sorg benodig.

Vertel u dokter indien u enige van die volgende opmerk:

Dikwels:

- Diarree, naarheid & braking

Minder dikwels:

- Urtikarie (jeukerige vel-erupsie)
- Purpura (bruin-rooi spikkels op die vel)
- Inflammasie van die niere
- Bloedabnormaliteite bv. neutropenie en trombositopenie, esinofilie, hemolitiese anemie
- Anafilaktiese skok (ernstige allergiese reaksie)
- Angioneurotiese edeem (vinnige opswel)
- Pseudomembraneuse kolitis (tipe van inflammasie van die kolon)
- Veranderinge in lewerfunksietoetse
- Erythema multiforme ('n rooi uitslag veroorsaak deur hipersensitiwiteit vir 'n medisyne of siekte of ander allergene),
- Artralgie (pyn in 'n gewrig) en mialgie (pyn in die spiere).
- Interstisiële nefritis (nefritis waar die interstisiële bindweefsel hoofsaaklik beïnvloed kan word)
- Baie rare gevalle van bloed- en vloeistofabnormaliteite (hoë anion gap metaboliese asidose) wat voorkom wanneer daar 'n toename is in plasma-

Applicant/PHCR: Innovata Pharmaceuticals Pty. Ltd.
Product Proprietary Name: SEPTAPEN 250
Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
Registration date: 8 February 1999

CTD, Module 1

asiditeit, wanneer flukloksasillien saam met parasetamol gebruik word, gewoonlik in die teenwoordigheid van risiko faktore (sien afdeling 2).

Sommige van hierdie reaksies kan vertraag word vir tot twee maande na die voltooiing van behandeling.

Frekwensie nie bekend:

- Ernstige velreaksie - 'n Rooi, skubberige uitslag met knoppe onder die vel en blasies (eksantemateuse pustulose).

Indien u enige ander newe-effekte opmerk wat nie in die biljet gemeld word nie, stel asseblief u dokter of apteker in kennis daarvan.

Rapporteer van newe-effekte

Indien u newe-effekte kry, raadpleeg u dokter of apteker. U kan ook die newe-effekte rapporteer aan SAHPRA via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte te rapporteer kan u help om meer inligting te voorsien omtrent die veiligheid van **SEPTAPEN 250**.

5. HOE OM SEPTAPEN 250 TE BERG

Berg alle medisyne buite die bereik van kinders.

Berg by of benede 25 °C, in 'n droë plek.

Berg in die oorspronklike verpakking.

Moenie die kapsules gebruik na die vervaldatum wat op die etiket meld word nie.

Moenie in die badkamer berg nie.

Neem alle ongebruikte medisynes terug na u apteker.

Date of PI: 09/05/2024



Applicant/PHCR: Innovata Pharmaceuticals Pty. Ltd.
Product Proprietary Name: SEPTAPEN 250
Dosage Form & Strength: Capsules, Flucloxacillin 250 mg
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CTD, Module 1

Moenie van ongebruikte medisynes ontslae raak deur dit in afvoerpype of rioolsisteme te gooi nie (bv. toilette).

6. Inhoud van die pakkie en ander inligting

Wat SEPTAPEN 250 bevat

Die aktiewe substans is flukloksasillien natrium.

Die ander bestanddele is:

Magnesiumstearaat.

Grootte 2 swart/rooi harde gelatien kapsule bestanddele:

Swart oksied, eritrosien, gelatien, rooi oksied, **titaniumdioksied**.

Hoe SEPTAPEN 250 lyk en inhoud van die pakkie

SEPTAPEN 250 kapsules is swart/rooi grootte "2" harde gelatien kapsules.

SEPTAPEN 250 is beskikbaar in:

Bruin glas bottels bevattende 20 of 100 kapsules.

20's, 40's en 100's gedrukte Alu/LDPE pasiënt-gereed pakkies.

PP/HDPE securitainers bevattende 20 of 100 kapsules.

Nie alle pakgroottes mag bemark word nie.

HOUER VAN SERTIFIKAAT VAN REGISTRASIE

Innovata Pharmaceuticals (Pty) Ltd

Crownwood Office Park,

Block D, Ground floor

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CTD, Module 1

100 Northern Parkway

Ormonde

Johannesburg

2091

Hierdie biljet was laas hersien

09/05/2024

REGISTRASIENOMMER

A 29/20.1.2/0550

Toegang tot die ooreenstemmende Professionele Inligting.

Volg die link vir die ooreenstemmende Professionele Inligting vir **SEPTAPEN:**

pi-pil-repository.innovata.co.za,

alternatiewelik skandeer asseblief die QR kode hieronder:

