Patient Information Leaflet

SCHEDULING STATUS

S4

ALLMOX S powder for oral suspension

ALLMOX SF powder for oral suspension

Amoxicillin

Contains sugar and sweetener

ALLMOX S 125 mg/ 5 ml:

Contains sugar: sorbitol 12 mg/5 ml

Contains sweetener: saccharin sodium 9 mg /5 ml

ALLMOX SF 250 mg/ 5 ml:

Contains sugar: sorbitol 12 mg/5 ml

Contains sweetener: saccharin sodium 9 mg /5 ml

Read all of this leaflet carefully before you start taking ALLMOX

• 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.

• **ALLMOX** 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 ALLMOX is and what it is used for

ALLMOX is an antibiotic, belonging to a group of medicines called ‘penicillins’.

ALLMOX is used to treat infections caused by bacteria in different parts of the body. **ALLMOX** may also be used in combination with other medicines to treat stomach ulcers.

2. What you need to know before you take ALLMOX

Do not take **ALLMOX**:

• if you are hypersensitive (allergic) to amoxicillin, penicillin or any of the other ingredients of **ALLMOX** (listed in section 6).

• if you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

• if you have infectious mononucleosis, also known as glandular fever (fever, sore throat, swollen glands and extreme tiredness). A high percentage of patients with mononucleosis who receive amoxicillin develop an erythematous skin rash.

Warnings and precautions

Take special care with **ALLMOX**:

• if you had seizures, have epilepsy or had inflammation of the membranes and fluids surrounding the brain and spinal cord (meningeal disorders). You might experience convulsions when taking high dosages of **ALLMOX**.

• if you have kidney problems or are not urinating regularly. Your doctor may need to change the dose of **ALLMOX** (see section 3 of this leaflet).

• if you had a skin rash that looks like measles. It may be more likely that you will have a severe skin reaction when taking **ALLMOX**.

• if you develop a Jarisch-Herxheimer's reaction. This reaction has been reported during amoxicillin treatment of syphilis or tick-borne diseases like Lyme disease.

Symptoms include high fever, a general feeling of discomfort, illness, or unease, nausea, vomiting, headache, muscle pain, aggravated skin rashes, fast heartbeat and chills.

• if you develop diarrhoea. This may happen while you are taking **ALLMOX**, or within a few months after you stop taking it. This may be a sign of a new infection. If you have diarrhoea that is watery or bloody, stop taking **ALLMOX** and call your doctor. Do not use anti-diarrhoea medicine unless your doctor tells you to.

• if you are having laboratory tests, because **ALLMOX** can affect the results of some of these tests.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking **ALLMOX**.

Other medicines and ALLMOX

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

• If you are taking allopurinol (used for gout) with **ALLMOX**, it may be more likely that you will have an allergic skin reaction.

• If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of **ALLMOX**.

• If you are taking medicines to help stop your blood from clotting (such as warfarin), you may need extra blood tests.

• If you are taking other antibiotics (such as tetracycline) **ALLMOX** may be less effective.

• If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) **ALLMOX** may cause an increase in side effects.

• If you are taking birth control pills, as **ALLMOX** may affect the efficacy of some of these pills.

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 this medicine.

ALLMOX is excreted in small quantities into breast milk and it is possible that your baby can experience diarrhoea and fungus infection. Breastfeeding while taking **ALLMOX** is not advised.

Driving and using machines

ALLMOX can have side effects and the symptoms (such as allergic reactions, dizziness and convulsions) may make you unfit to drive or use machinery. Do not engage in the above activities until you are aware of the measure to which **ALLMOX** affects you.

ALLMOX contains sorbitol

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

3. How to take ALLMOX

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

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

• Shake the bottle before each dose.

• Space the doses evenly during the day, at least 4 hours apart.

• **ALLMOX** may be taken with or without food.

The usual dose is:

Children under 12 years

• Your doctor will advise you how much **ALLMOX** you should give to your baby or child depending on your child's age.

• The usual dose for children 6 months to 10 years of age is equivalent of 125 mg (i.e. 5 ml of 125 mg/5 ml) three times a day.

• 0 – 6 months: 62,5 mg (2,5 ml of 125 mg/5 ml) three times a day.

Adults and children over 12 years

• The usual dose of **ALLMOX** is 250 mg to 500 mg three times a day. Depending on the severity and type of infection, another dose can be given to you.

Your doctor will tell you how long your treatment with **ALLMOX** will last. Do not stop treatment early because if some bacteria survive they can cause the infection to come back.

If you take more ALLMOX than you should

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

If you have taken too much **ALLMOX**, signs might be an upset stomach (nausea, vomiting or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems urinating.

Take the medicine to show the doctor.

If you forget to take ALLMOX

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

Take the dose as soon as you remember and wait about 4 hours before you take the next dose.

If you stop taking ALLMOX

Keep taking **ALLMOX** for as long as your doctor has told you to, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they

can cause the infection to come back. You should go back to see the doctor if you finish treatment and you still feel unwell.

4. Possible side effects

ALLMOX can have side effects.

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

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

- allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue, body and breathing difficulties. These can be serious and occasionally deaths have occurred.
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

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

• rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain (arthritis) and kidney problems;

• a delayed allergic reaction can occur usually 7 to 12 days after having **ALLMOX**, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes especially under the arms;

• a skin reaction known as erythema multiforme where you may develop: itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, hive-like raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals. You may have a fever and be very tired;

• other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches and body aches;

• flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS));

• fever, chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells;

• the Jarisch-Herxheimer reaction which occurs during treatment with **ALLMOX** for Lyme disease or syphilis and causes fever, chills, headache, muscle pain and skin rash;

• inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever;

• serious liver side effects may occur. They are mainly associated with people having treatment over a long period. You must tell your doctor urgently if you get:

- severe diarrhoea with bleeding,
- blisters, redness or bruising of the skin,
- darker urine or paler stools
- yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice.

- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

These can happen while taking **ALLMOX** or for up to several weeks after taking **ALLMOX**. 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;

• skin rash.

Less frequent

• thrush (a yeast infection of the vagina, mouth or skin folds);

• Low number of white blood cells, low number of cells involved with blood clotting, blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or you cut yourself;

• fits (convulsions), dizziness, hyperactivity;

• vomiting, inflammation of the colon, tongue may have a hairy, black appearance;

• skin reactions such as rashes;

• kidney problems.

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 Reactions 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 **ALLMOX**.

5. How to store ALLMOX

Store all medicines out of reach of children.

• Store the dry powder at or below 25 °C.

• Once the dry powder is mixed with water, store for 14 days at 2 °C to 8 °C in a refrigerator.

• Store in the original package.

• Keep the container tightly closed.

• Do not use after the expiry date stated on the 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 ALLMOX contains

• The active substance is amoxicillin.

• The other ingredients are colloidal anhydrous silica (E551), colour Sunset Yellow Supra CI15985 (E110), saccharin sodium (E954), sodium citrate (E331), sorbitol, Tutti Fruitti flavour (AP0551), xanthan gum (E415).

What ALLMOX looks like and contents of the pack

ALLMOX is a white to off white powder forming an orange suspension after reconstitution with water. The resulting suspension has a characteristic flavour.

ALLMOX oral powder for suspension is filled in a HDPE bottle with a white polypropylene child resistant closure with an induction sealing liner in an outer carton.

Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) Ltd

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Ormonde

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2091

South Africa

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Registration numbers

Allmox S 125: 36/20.1.2/0117

Allmox SF 250: 36/20.1.2/0118

Access to the corresponding Professional Information is contained in the packaging or

Follow the link for the corresponding Professional Information for ALLMOX S and ALLMOX SF: pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below:

Pasiënt Inligtingbiljet

SKEDULERINGSTATUS

S4

ALLMOX S poeier vir orale suspensie

ALLMOX SF poeier vir orale suspensie

Amoksisillien

Bevat suiker en versoeter

ALLMOX S 125 mg/ 5 ml:

Bevat suiker: sorbitol 12 mg/5 ml

Bevat versoeter: sakkarien natrium 9 mg /5 ml

ALLMOX SF 250 mg/ 5 ml:

Bevat suiker: sorbitol 12 mg/5 ml

Bevat versoeter: sakkarien natrium 9 mg /5 ml

Lees die volledige biljet noukeurig deur voordat u begin om ALLMOX 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.

• **ALLMOX** 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 ALLMOX is en waarvoor dit gebruik word

ALLMOX is ‘n antibiotika wat behoort aan ‘n groep van medisynes wat genoem word ‘penisilliene’.

ALLMOX word gebruik om infeksies te behandel wat veroorsaak word deur bakterieë in verskillende dele van die liggaam. **ALLMOX** kan ook gebruik word in kombinasie met ander medisynes vir die behandeling van maagsere.

2. Wat u behoort te weet voordat u ALLMOX neem

Moenie **ALLMOX** neem:

- indien u hipersensitief (allergies) is vir amoksisillien, penisillien of enige van die ander bestanddele van **ALLMOX** nie (aangedui in afdeling 6).
- indien u ooit ‘n allergiese reaksie gehad het vir enige antibiotika. Dit kan insluit ‘n veluitslag of opswel van die gesig of keel.
- indien u infektiewe mononukleose het, ook bekend as klierkoors (koors, seerkeel, geswelde kliere en uiterste moegheid). ‘n Hoë persentasie van pasiënte met mononukleose wat amoksisillien ontvang, ontwikkel ‘n eritemateuse veluitslag.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met **ALLMOX**:

- indien u siekte-aanvalle gehad het, epilepsie, of inflammasie van die membrane en vloeistof om die brein en spinale koord (meningeale afwykings). U mag konvulsies ondervind wanneer u hoë doserings van **ALLMOX** neem.
- indien u nierprobleme het of nie gereëld urineer nie. U dokter kan dit nodig vind om die dosering van **ALLMOX** te verander (sien afdeling 3 van hierdie biljet).
- indien u ‘n veluitslag het wat lyk soos masels. Dit is waarskynlik dat u ‘n ernstige

velreaksie sal kry wanneer u **ALLMOX** neem.

• indien u Jarisch-Herxheimer se reaksie ontwikkel. Hierdie reaksie was gerapporteer gedurende amoksisillien-behandeling van sifillis of bosluisvlek siektes soos Lyme se siekte. Simptome sluit in hoë koors, 'n algemene gevoel van ongemak, siek gevoel of ongemak, naarheid, braking, hoofpyn, spierpyn, agteruitgang van veluitslag, vinnige hartklop en koue rillings.

• indien u diarree ontwikkel. Dit kan gebeur terwyl u **ALLMOX** neem of binne 'n paar maande nadat u dit gestaak het. Dit kan 'n teken wees van 'n nuwe infeksie. Indien u diarree het wat waterig of bloederig is, staak die gebruik van **ALLMOX** en raadpleeg u dokter. Moenie antidiarree medisyne gebruik nie, tensy u dokter dit aanbeveel.

• indien u laboratoriumtoetse moet laat doen, omdat **ALLMOX** die resultate van sommige van hierdie toetse kan beïnvloed.

Indien u nie seker is of enige van die bogemelde op u van toepassing is nie, raadpleeg u dokter of apteker voordat u **ALLMOX** neem.

Ander medisynes en ALLMOX

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

• Indien u allopurinol neem (word gebruik vir jig) met **ALLMOX**, is dit meer waarskynlik dat u 'n allergiese velreaksie sal ontwikkel.

• Indien u probenesied neem (word gebruik vir jig), sal u dokter moontlik besluit om u dosis van **ALLMOX** aan te pas.

• Indien u medisynes neem om te help met u bloedstolling (soos warfarien), kan u moontlik ekstra bloedtoetse benodig.

• Indien u ander antibiotika neem (soos tetrasikliene) kan **ALLMOX** minder effektief wees.

• Indien u metotreksaat neem (wat gebruik word vir die behandeling van kanker en ernstige psoriase) kan **ALLMOX** 'n toename in newe-effekte veroorsaak.

• Indien u geboortebeperking tablette neem, omdat **ALLMOX** die effektiwiteit van sommige van hierdie tablette kan beïnvloed.

Swangerskap en borsvoeding

Indien u swanger is of borsvoed, dink dat u swanger kan wees of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgvoorsiener vir advies voordat hierdie medisyne geneem word.

ALLMOX word uitgeskei in klein hoeveelhede in die borsmelk en dit is moontlik dat u baba diarree kan kry en fungus-infeksie. Borsvoeding terwyl u **ALLMOX** gebruik word nie aanbeveel nie.

Bestuur en gebruik van masjinerie

ALLMOX kan newe-effekte veroorsaak en die simptome (soos allergiese reaksies, duiseligheid en konvulsies) kan veroorsaak dat u onbevoeg is om te bestuur of masjinerie te gebruik. Moenie deelneem aan die bogemelde aktiwiteite nie totdat u weet tot watter mate **ALLMOX** u beïnvloed

ALLMOX bevat sorbitol

Sorbitol kan gastroïntestinale ongemak en ligte lakserende effek veroorsaak.

3. Hoe om ALLMOX te neem

Moenie medisynes wat vir u voorgeskryf is met enige ander persoon deel nie.

Neem **ALLMOX** altyd soos u dokter of apteker u aanbeveel het. Raadpleeg u dokter of apteker indien u nie seker is nie.

• Skud die bottel voor elke dosering.

• Verdeel die doserings eweredig gedurende die dag, met ten minste 4 ure tussenin.

• **ALLMOX** kan met of sonder voedsel geneem word.

Die gewone dosering is:

Kinders onder 12 jaar oud

• U dokter sal u inlig hoeveel **ALLMOX** u aan u baba of kind moet gee afhangende van u kind se ouderdom.

• Die gewone dosis vir kinders 6 maande tot 10 jaar oud is ekwivalent aan 125 mg (d.w.s. 5 ml van 125 mg/5 ml) drie keer per dag.

• 0 – 6 maande: 62,5 mg (2,5 ml van 125 mg/5 ml) drie keer per dag.

Volwassenes en kinders oor 12 jaar oud

• Die gewone dosis van **ALLMOX** is 250 mg tot 500 mg drie keer per dag.

Afhangende van die erns en tipe van infeksie, kan nog ‘n dosis gegee word.

U dokter sal u inlig hoe lank u behandeling met **ALLMOX** sal duur. Moenie die behandeling te vroeg staak nie omdat sommige bakterieë sal oorleef, wat kan veroorsaak dat die infeksie weer sal terugkeer.

Indien u meer ALLMOX 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 te veel **ALLMOX** geneem het, kan daar tekens wees van ‘n omgekrapte maag (naarheid, braking of diarree) of kristalle in die uriene, wat gesien kan word as wolkerige uriene of probleme om te urineer.

Neem die medisyne saam om vir die dokter te wys.

Indien u vergeet het om ALLMOX te neem

Moenie ‘n dubbele dosis neem om op te maak vir die individuele dosisse wat u vergeet het nie.

Neem die dosis so gou as wat u onthou en wag vir ongeveer 4 ure voordat u die volgende dosis neem.

Indien u die neem van ALLMOX staak

Hou aan om **ALLMOX** te neem vir so lank as wat u dokter aanbeveel het, selfs indien u beter voel. U het elke dosering nodig om die infeksie te behandel. Indien sommige bakterieë oorleef, kan dit veroorsaak dat die infeksie weer terugkom. U moet teruggaan na die dokter sodra die behandeling voltooi is en u nog siek voel.

4. Moontlike newe-effekte

ALLMOX kan newe-effekte hê.

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

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

- allergiese reaksies, die tekens kan insluit die jeuk van u vel of uitslag, opswel van die gesig, lippe, tong, liggaam en asemhalingsprobleme. Hierdie kan ernstig wees en sterftes het voorgekom.
- borspyn in die konteks van allergiese reaksies, wat ‘n simptoom kan wees van allergies veroorsaakte kardiale infarkt (Kounis sindroom).

Hierdie is almal baie ernstige newe-effekte. Indien u dit het, het u ‘n baie ernstige reaksie gehad met **ALLMOX**. U mag dringende mediese aandag benodig of hospitalisering.

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

• uitslag of speldepunt plat rooi ronde spikkels onder die veloppervlakte of kneusing van die vel. Dit is weens inflammasie van bloedvaat wande, as gevolg van ‘n allergiese reaksie. Dit kan geassosieer wees met gewrigspyn (artritis) en nierprobleme;

• ‘n vertraagde allergiese reaksie kan voorkom gewoonlik 7 tot 12 dae na die neem van **ALLMOX**, sommige tekens kan insluit: uitslag, koors, gewrigspyn en vergroting van die limfnode, veral onder die arms;

• ‘n velreaksie wat bekend staan as erythema multiforme waar u die volgende kan ontwikkel: jeukerige rooi-pers kolle op die vel, veral die handpalms of voetsole, veluitslag tipe opgeswelde areas op die vel, gevoelige areas op die oppervlaktes van die mond, oë en genitale areas. U kan koors hê en baie moeg voel;

• ander ernstige velreaksies kan insluit: veranderinge in velkleur, knoppies onder die vel, blasies, pustulle, afdop, rooiheid, pyn, jeuk, afskilfering. Hierdie kan geassosieer wees met koors, hoofpyn en liggaamspyn;

• griepagtige simptome met ‘n uitslag, koors, opgeswelde kliere en abnormale bloedtoets resultate (insluitend verhoogde witbloedselle en lewerensieme) (Medisyne Reaksie met Esinofilie en Sistemiese Simptome (DRESS));

• koors, koue rillings, ‘n seerkeel of ander tekens van ‘n infeksie of indien u maklik kneus. Hierdie kan tekens wees van ‘n probleem met u bloedselle;

• die Jarisch-Herxheimer reaksie wat voorkom gedurende behandeling met **ALLMOX** vir Lyme se siekte, of sifillis, en koors veroorsaak, koue rillings, hoofpyn, spierpyn en veluitslag;

• inflammasie van die dikderm (kolon) met diarree (soms bevat dit bloed), pyn en koors;

• ernstige lewer newe-effekte kan voorkom. Dit kan hoofsaaklik geassosieer word met persone wat behandeling oor ‘n lang periode ontvang het.

Vertel u dokter dringend indien u die volgende ontwikkel:

- ernstige diarree met bloeding,

- blasies, rooiheid of kneusing van die vel,
- donker uriene of ligter stoelgang,
- geel verkleuring van die vel of die wit van die oë (geelsug). Sien ook anemie hieronder wat geelsug tot gevolg kan hê,
- uitslag met blasies in ‘n sirkel met ‘n sentrale kors of soos ‘n string pêrels (lineêr IgA siekte).

Hierdie kan gebeur terwyl u **ALLMOX** neem of vir tot etlike weke nadat **ALLMOX** geneem is. Hierdie is almal baie ernstige newe-effekte. U kan moontlik dringende mediese sorg benodig.

Vertel u dokter indien u enige van die volgende opmerk:

Dikwels

- diarree, naarheid;
- veluitslag.

Minder dikwels

- sproei (‘n gis-infeksie van die vagina, mond of voue van die vel);
- klein hoeveelheid van witbloedselle, klein hoeveelheid van selle betrokke met bloedstolling, bloed kan langer neem om te stol as normaalweg. U kan dit agterkom indien u neus begin bloei of indien u uself raak sny;
- siekte-aanvalle (konvulsies), duiseligheid, hiperaktiwiteit;
- braking, inflammasie van die kolon, tong kan ‘n harige, swart voorkoms wys;
- velreaksies soos uitslag;
- nierprobleme.

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

Rapporteer van newe-effekte

Indien u newe-effekte ontwikkel, raadpleeg u dokter, apteker of verpleegkundige.

U kan ook newe-effekte rapporteer aan SAHPRA via die "**6.04 Adverse Drug Reactions 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 **ALLMOX**.

5. Hoe om ALLMOX te berg

Bêre alle medisynes buite die bereik van kinders.

• Berg die droë poeier by of benede 25 °C.

• Sodra die droë poeier gemeng is met water, berg vir 14 dae by 2 °C tot 8 °C in 'n koelkas.

• Berg in die oorspronklike verpakking.

• Hou die houer dig toe.

• Moenie gebruik na die vervaldatum gemeld op die etiket nie.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie enige ongebruikte medisyne in afvoerpype of rioolsisteme gooi nie (bv. toilette).

6. Inhoud van die pakkie en ander inligting

Wat ALLMOX bevat

• Die aktiewe bestanddeel is amoksisillien.

• Die ander bestanddele is kolloïdale anhidriese silika (E551), kleur Sunset Yellow Supra CI15985 (E110), sakkarien natrium (E954), natriumsitraat (E331), sorbitol, Tutti Fruitti geur (AP0551), xanthan gom (E415).

Hoe ALLMOX lyk en inhoud van die pakkie

ALLMOX is ‘n wit tot naaswit poeier wat ‘n oranje suspensie vorm na herkonstitusie met water. Die gevolglike suspensie het ‘n kenmerkende geur.

ALLMOX orale poeier vir suspensie is gevul in ‘n HDPE bottel met ‘n wit polipropileen kind-bestande sluiter met ‘n induksie seël belyner in ‘n buitenste karton.

Houer van Sertifikaat van Registrasie

Innovata Pharmaceuticals (Pty) Ltd

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

Suid-Afrika

Hierdie biljet was laas hernu in

27 November 2024

Registrasienommers

ALLMOX S 125: 36/20.1.2/0117

ALLMOX SF 250: 36/20.1.2/0118

Toegang tot die ooreenstemmende Professionele Inligting is ingesluit in die verpakking,

of

Volg die skakel vir die ooreenstemmende Professionele Inligting vir **ALLMOX S** en **ALLMOX SF**: pi-pil-repository.innovata.co.za, alternatief skandeer asseblief die QR kode hieronder: