SCHEDULING STATUS: S4

ADCO-AMOXYCILLIN 125 mg/5 ml (SUSPENSION)
ADCO-AMOXYCILLIN 250 mg/5 ml (SUSPENSION)
ADCO-AMOXYCILLIN 250 mg (CAPSULES)
ADCO-AMOXYCILLIN 500 mg (CAPSULES)
Amoxicillin
Contains sugar: Sucrose 3,05 g per 5 ml (for the 125 mg/5 ml suspension).
Contains sugar: Sucrose 3,15 g per 5 ml (for the 250 mg/5 ml suspension).

Read all of this leaflet carefully before you start taking / using / are given ADCO-AMOXYCILLIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ADCO-AMOXYCILLIN 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 ADCO-AMOXYCILLIN is and what it is used for
2. What you need to know before you take ADCO-AMOXYCILLIN
3. How to take ADCO-AMOXYCILLIN
4. Possible side effects
5. How to store ADCO-AMOXYCILLIN
6. Contents of the pack and other information

1. What ADCO-AMOXYCILLIN is and what it is used for

ADCO-AMOXYCILLIN belongs to a group of antibiotics called ‘penicillins’. These antibiotics work by killing the bacteria that are causing your infection.

2. What you need to know before you take ADCO-AMOXYCILLIN

Do not take ADCO-AMOXYCILLIN:

- if you are hypersensitive (allergic) to amoxicillin or any of the other ingredients of ADCO-AMOXYCILLIN (listed in section 6).
- if you have had a serious allergic reaction to any antibiotics. Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or

tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.

Warnings and precautions

Take special care with ADCO-AMOXYCILLIN:

- if you have kidney problems;
- if you have glandular fever (fever, sore throat, swollen glands and extreme tiredness);
- if you are breastfeeding or intend to breastfeed

ADCO-AMOXYCILLIN passes into breast milk and can be used only with caution during breastfeeding.

If you have or have had any medical conditions, including:

- liver problems;
- lymphatic leukaemia (a type of cancer of the blood and bone marrow);
- glandular fever which can cause symptoms such as fatigue, swollen glands, a sore throat;
- a history of seizures;
- stomach or bowel problems;
- a history of allergic problems, including hay fever.

Having urine or blood tests:

- Urine tests (glucose) or blood tests for liver function.
- Oestriol tests (used during pregnancy to check that the baby is developing normally). This is because ADCO-AMOXYCILLIN can affect the results of these tests.

Other medicines and ADCO-AMOXYCILLIN

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

Tell your doctor if you are taking any of the following medicines:

- Medicines used to treat gout (e.g. probenecid or allopurinol). It may be more likely that you will have an allergic skin reaction or your doctor may decide to adjust the dose of ADCO-AMOXYCILLIN.
- Medicines used to prevent blood clots from the coumarin class (e.g. warfarin) as you may need extra blood tests.
- Methotrexate, a medicine used to treat arthritis and some types of cancers. ADCO-AMOXYCILLIN may cause an increase in side effects.
- Oral contraceptives (birth control pills). You are advised to take supplementary nonhormonal

contraceptive measures e.g. condoms

- Other antibiotics (e.g. tetracycline), ADCO-AMOXYCILLIN may be less effective.

Pregnancy, breastfeeding and fertility

The safety of ADCO-AMOXYCILLIN during pregnancy has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

ADCO-AMOXYCILLIN is excreted in breast milk and should be used with caution when taken by breastfeeding women.

ADCO-AMOXYCILLIN may reduce the effectiveness of some birth control pills, and patients should use an additional method of contraception e.g. condoms (see section 'Other medicines and ADCO-AMOXYCILLIN').

Driving and using machines

It is not always possible to predict to what extent ADCO-AMOXYCILLIN may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ADCO-AMOXYCILLIN affects you.

ADCO-AMOXYCILLIN may cause allergic reactions, dizziness or convulsions and may thus have an effect on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

ADCO-AMOXYCILLIN contains:

Sucrose:

ADCO-AMOXYCILLIN suspension contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ADCO-AMOXYCILLIN.

Sodium methyl hydroxybenzoate:

ADCO-AMOXYCILLIN suspension contains 0,08% *m/v* sodium methyl hydroxybenzoate. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). It may also cause allergic reactions (possibly delayed).

3. How to take ADCO-AMOXYCILLIN

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

Always take ADCO-AMOXYCILLIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults:

- The average adult dose for ADCO-AMOXYCILLIN is 750 mg - 1,5 g/day, but in serious infections up to 6 g daily has been administered.

Paediatric population:

- **Children 2 - 10 years:**

125 mg (5 ml of 125 mg/5 ml suspension) three times a day.

- **Children 6 months - 2 years:**

125 mg (5 ml of 125 mg/5 ml suspension) three times a day.

- **Infants 0 - 6 months:**

62,5 mg (2,5 ml of 125 mg/5 ml suspension) three times a day.

- **Premature infants 1,0 - 2,5 kg:**

30,0 - 62,5 mg (quarter to half medicine measure of 125 mg/5 ml suspension) once daily for the first 1 - 2 weeks depending on the size and maturity of the infant, thereafter the dose may be given 2 – 3 times daily.

Your doctor will tell you how long your treatment with ADCO-AMOXYCILLIN will last. If you have the impression that the effect of ADCO-AMOXYCILLIN is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO-AMOXYCILLIN 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 forget to take ADCO-AMOXYCILLIN

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

If you stop taking ADCO-AMOXYCILLIN

Do not stop treatment early because the infection can come back. Take ADCO-AMOXYCILLIN until the treatment is finished, even if you feel better.

4. Possible side effects

ADCO-AMOXYCILLIN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- inflammation of the protective membrane surrounding the brain (aseptic meningitis);
- 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 allergic reaction to ADCO-AMOXYCILLIN. 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:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin;
- a widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis);
- a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis);
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS);
- a skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme);
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

Drug-induced enterocolitis syndrome (DIES):

- DIES has been reported mainly in children receiving amoxicillin. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after medicine intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea
- Diarrhoea
- Skin rash

Less frequent side effects:

- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body;
- fever, joint pain, swollen glands in the neck, armpit or groin;
- inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever;
- jaundice, caused by increase of bilirubin (a substance produced in the liver) in the blood which may make your skin and whites of the eyes appear yellow;
- inflammation of the liver (hepatitis);
- convulsions (in people taking high doses of ADCO-AMOXYCILLIN or who have kidney problems);
- inflammation and soreness of the mouth, tongue or lips;
- black tongue which looks hairy;
- vomiting;
- thrush (Candida - a yeast infection of the vagina, mouth or skin folds);
- indigestion;
- dizziness;
- headache;
- a state of excessive restlessness;
- tooth discolouration;
- crystals in urine leading to acute renal injury;
- inflammation of tubes in the kidney.

Frequency is unknown:

- increase in some substances (enzymes) produced by the liver;
- severe reduction in the number of white blood cells;
- low number of red blood cells (haemolytic anaemia);
- low number of cells involved in blood clotting.

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. By reporting side effects, you can help provide more information on the safety of ADCO-AMOXYCILLIN.

You may also report to Adcock Ingram Limited using the following e-mail address: Adcock.AEReports@adcock.com.

5. How to store ADCO-AMOXYCILLIN

Capsules and powder must be:

- stored at or below 25 °C.
- protected from moisture.

Reconstituted suspension:

- Once reconstituted, ADCO-AMOXYCILLIN suspension must be used within 7 days kept at temperatures not exceeding 25 °C or used within fourteen days kept under refrigeration (2 °C - 8°C).
- Do not freeze.
- Store in the original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Store all medicines out of reach of children.

6. Contents of the pack and other information

What ADCO-AMOXYCILLIN contains

- The active substance is:

Amoxicillin

- The other ingredients are:

Capsules:

Colloidal anhydrous silica

Magnesium stearate

Cap and Body:

Brilliant Blue FCF

Erythrosine BS

Titanium dioxide (CI No. 77891)

Sunset Yellow

Sodium lauryl sulphate

Gelatin

Composition of Imprinting White Ink

Titanium dioxide (CI No. 77891)

Shellac

Isopropyl alcohol

Alcohol

Tween 80

Suspensions:

Quinoline yellow supra (CI No. 47005)

Lemon dry flavour

Apricot dry flavour

Sodium methyl hydroxybenzoate

Carmellose sodium

Sodium citrate

Colloidal anhydrous silica

Sucrose

What ADCO-AMOXYCILLIN looks like and contents of the pack

Powders for oral suspension:

Powder for oral suspension is available in clear glass and white HDPE bottles providing 100 ml or 75 ml of the suspension when reconstituted.

Capsules:

The 250 mg capsules are packed in containers of 15, 100, 500 and 1000 capsules.

The 500 mg capsules are packed in containers of 15, 100 and 1000 capsules, and blister packs of 15 and 100 capsules.

Not all pack types and pack sizes are marketed.

Holder of Certificate of Registration

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ADCO-AMOXYCILLIN 125 mg/5 ml: X/20.1.2/198
ADCO-AMOXYCILLIN 250 mg/5 ml: X/20.1.2/199
ADCO-AMOXYCILLIN 250 mg: X/20.1.2/196
ADCO-AMOXYCILLIN 500 mg: X/20.1.2/197

PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: S4

ADCO-AMOXYCILLIN 125 mg/5 ml (SUSPENSIE)
ADCO-AMOXYCILLIN 250 mg/5 ml (SUSPENSIE)
ADCO-AMOXYCILLIN 250 mg (KAPSULES)
ADCO-AMOXYCILLIN 500 mg (KAPSULES)
Amoksisillien
Bevat suiker: Sukrose 3,05 g per 5 ml (vir die 125 mg/5 ml suspensie).
Bevat suiker: Sukrose 3,15 g per 5 ml (vir die 250 mg/5 ml suspensie).

Lees hierdie hele biljet noukeurig deur voordat u ADCO-AMOXYCILLIN begin neem / gebruik / ontvang

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker.
- ADCO-AMOXYCILLIN is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

1. Wat ADCO-AMOXYCILLIN is en waarvoor dit gebruik word
2. Wat u moet weet voordat u ADCO-AMOXYCILLIN neem
3. Hoe om ADCO-AMOXYCILLIN te neem
4. Moontlike newe-effekte
5. Hoe om ADCO-AMOXYCILLIN te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat ADCO-AMOXYCILLIN is en waarvoor dit gebruik word

ADCO-AMOXYCILLIN behoort tot 'n groep antibiotika wat 'penisilliene' genoem word. Hierdie antibiotika werk deur die bakterieë wat u infeksie veroorsaak, dood te maak.

2. Wat u moet weet voordat u ADCO-AMOXYCILLIN neem

Moenie ADCO-AMOXYCILLIN neem nie:

- indien u hipersensitief (allergies) is vir amoksisillien of enige van die ander bestanddele van ADCO-AMOXYCILLIN (gelys in afdeling 6).
- indien u 'n ernstige allergiese reaksie op enige antibiotika gehad het. Sommige van die simptome van 'n allergiese reaksie kan asma, hygende asemhaling, kortasem, swelling van die

gesig, lippe of tong insluit wat probleme met sluk of asemhaling veroorsaak, veluitslag, jeuk of galbulte insluit.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met ADCO-AMOXYCILLIN:

- indien u nierprobleme het;
- indien u klierkoors het (koors, seer keel, geswelde kliere en uiterste moegheid);
- indien u borsvoed of van plan is om te borsvoed. ADCO-AMOXYCILLIN word in borsmelk afgeskei en kan slegs met versigtigheid tydens borsvoeding gebruik word.

Indien u enige mediese toestande het, of gehad het, insluitend:

- lewerprobleme;
- limfatiese leukemie ('n tipe kanker van die bloed en beenmurg);
- klierkoors wat simptome soos moegheid, geswelde kliere en seer keel kan veroorsaak;
- 'n geskiedenis van stuipaanvalle;
- maag- of dermprobleme;
- 'n geskiedenis van allergiese probleme, insluitend hooikoors.

Ondergaan van urien- of bloedtoetse:

- Urientoetse (glukose) of bloedtoetse vir lewerfunksie.
- Estrioltoetse (word tydens swangerskap gebruik om te kyk of die baba normaal ontwikkel). Dit is omdat ADCO-AMOXYCILLIN die resultate van hierdie toetse kan beïnvloed.

Ander medisyne en ADCO-AMOXYCILLIN

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

Lig u dokter in indien u enige van die volgende medisyne neem:

- Medisyne wat gebruik word om jig te behandel (bv. probenesied of allopurinol). Dit kan meer waarskynlik wees dat u 'n allergiese velreaksie sal hê, of u dokter kan besluit om die dosis ADCO-AMOXYCILLIN aan te pas.
- Medisyne uit die kumarien-klas (bv. warfarien), wat gebruik word om bloedklonte te voorkom, aangesien u ekstra bloedtoetse benodig.
- Metotreksaat, 'n medisyne wat gebruik word om artritis en sommige soorte kankers te behandel. ADCO-AMOXYCILLIN kan 'n toename in newe-effekte veroorsaak.
- Orale voorbehoedmiddels (geboortebeperkingspille). U word aangeraai om aanvullende nie-

hormonale voorbehoedmaatreëls te neem, bv. kondome

- Ander antibiotika (bv. tetrasiklien), ADCO-AMOXYCILLIN kan minder effektief wees.

Swangerskap, borsvoeding en vrugbaarheid

Die veiligheid van ADCO-AMOXYCILLIN tydens swangerskap is nie vasgestel nie.
Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.
ADCO-AMOXYCILLIN word in borsmelk uitgeskei en moet met versigtigheid gebruik word wanneer dit deur borsvoedende vroue geneem word.
ADCO-AMOXYCILLIN kan die doeltreffendheid van sommige geboortebeperkingspille verminder, en pasiënte moet 'n addisionele metode van voorbehoeding gebruik, bv. kondome (sien afdeling “Ander medisyne en ADCO AMOXYCILLIN”).

Bestuur en gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel in watter mate ADCO-AMOXYCILLIN met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie betrokke raak by bestuur van ‘n voertuig of masjinerie hanteer voordat u bewus is van die mate waartoe ADCO-AMOXYCILLIN u beïnvloed nie.
ADCO-AMOXYCILLIN kan allergiese reaksies, duiseligheid of stuiptrekkings veroorsaak en kan dus 'n uitwerking hê op verstandelike en/of fisiese vermoëns om take of aktiwiteite uit te voer of deur te voer wat verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie vereis.

ADCO-AMOXYCILLIN bevat:

Sukrose:

ADCO-AMOXYCILLIN suspensie bevat sukrose wat 'n effek op die beheer van u bloedsuiker kan hê indien u diabetes mellitus het. Indien u deur u dokter ingelig is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u ADCO-AMOXYCILLIN neem.

Natriummetielhidroksibensoaat:

ADCO-AMOXYCILLIN suspensie bevat 0,08 % *m/v* natriummetielhidroksibensoaat. Bensoaatsout kan geelsug (vergeling van die vel en oë) by pasgebore babas (tot en met 4 weke oud) verhoog. Dit kan ook allergiese reaksies veroorsaak (moontlik vertraagde reaksie).

3. Hoe om ADCO-AMOXYCILLIN te neem

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd ADCO-AMOXYCILLIN presies soos u dokter of apteker u ingelig het. Raadpleeg u

dokter of apteker indien u nie seker is nie.

Die algemene dosis is:

Volwassenes:

- Die gemiddelde volwasse dosis vir ADCO-AMOXYCILLIN is 750 mg - 1,5 g/dag, maar by ernstige infeksies is tot 6 g daagliks toegedien.

Pediatriese bevolking:

- **Kinders 2 - 10 jaar:**

125 mg (5 ml van die 125 mg/5 ml suspensie) drie keer per dag.

- **Kinders 6 maande - 2 jaar:**

125 mg (5 ml van die 125 mg/5 ml suspensie) drie keer per dag.

- **Babas 0 - 6 maande:**

62,5 mg (2,5 ml van die 125 mg/5 ml suspensie) drie keer per dag.

- **Premature babas 1,0 - 2,5 kg:**

30,0 - 62,5 mg (kwart tot half medisynemate van die 125 mg/5 ml suspensie) een keer per dag vir die eerste 1 - 2 weke, afhangende van die grootte en ontwikkeling van die baba, daarna kan die dosis 2 - 3 keer per dag gegee word.

U dokter sal u inlig hoe lank u behandeling met ADCO-AMOXYCILLIN sal duur. Indien u die indruk het dat die effek van ADCO-AMOXYCILLIN te sterk of te swak is, lig u dokter of apteker in.

Indien u meer ADCO-AMOXYCILLIN neem as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u vergeet om ADCO-AMOXYCILLIN te neem

Moenie 'n dubbele dosis neem / ontvang om vergete individuele dosisse op te maak nie.

Indien u ophou om ADCO-AMOXYCILLIN te neem

Moenie die behandeling vroegtydig stop nie, want die infeksie kan terugkom. Neem ADCO-AMOXYCILLIN totdat die behandeling voltooi is, selfs al voel u beter.

4. Moontlike newe-effekte

ADCO-AMOXYCILLIN kan newe-effekte hê.

Nie alle newe-effekte wat vir ADCO-AMOXYCILLIN aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u

ADCO-AMOXYCILLIN neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak ADCO-AMOXYCILLIN en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal;
- veluitslag of jeuk;
- floute;
- inflammasie van die beskermende membraan rondom die brein (aseptiese breinvliesontsteking);
- borspyn in die konteks van allergiese reaksies, wat 'n simptoom kan wees van hartinfarksie wat deur allergie veroorsaak word (Kounis-sindroom).

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op ADCO-AMOXYCILLIN gehad. U het dalk dringende mediese hulp of hospitalisasie nodig.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- 'n wydverspreide veluitslag met blase en afskilferende vel, veral rondom die mond, neus, oë en geslagsdele (Stevens-Johnson se sindroom), en 'n ernstiger vorm, wat uitgebreide afskilfering van die vel veroorsaak;
- 'n wydverspreide rooi veluitslag met klein etterbevattende blase (bulleuse afskilferende dermatitis);
- 'n rooi, skubberige uitslag met knoppe onder die vel en blase (eksantemateuse pustulose);
- griepagtige simptome met 'n veluitslag, koors, geswelde kliere en abnormale bloedtoetsresultate (insluitend verhoogde witbloedselle (eosinofilie) en lewerensieme) (Geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS);
- 'n veluitslag, wat blase kan vorm, en lyk soos klein teikens (sentrale donker kolle omring deur 'n ligter area, met 'n donker ring om die rand – veelvuldige eriteem);
- veluitslag met blase wat in 'n sirkel gerangskik is met sentrale korsvorming of soos 'n string pêrels (lineêre IgA-siekte).

Geneesmiddel-geïnduseerde enterokolitis sindroom (GIES):

- GIES is hoofsaaklik aangemeld by kinders wat amoksisillien ontvang. Dit is 'n sekere soort allergiese reaksie met die mees algemene simptoom van herhalende braking (1-4 ure na

medisyne-inname). Verdere simptome kan buikpyn, lusteloosheid, diarree en lae bloeddruk insluit.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Gereelde newe-effekte:

- Naarheid
- Diarree
- Veluitslag

Minder gereelde newe-effekte:

- inflammasie van bloedvate (vaskulitis) wat sigbaar kan wees as rooi of pers geswelde kolle op die vel, maar wat ook ander dele van die liggaam kan beïnvloed;
- koors, gewrigspyn, geswelde kliere in die nek, oksel of lies;
- inflammasie van die dikderm, wat waterige diarree veroorsaak, gewoonlik met bloed en slym, maagpyn en/of koors;
- geelsug, veroorsaak deur ‘n verhoging van bilirubien ('n stof wat in die lewer geproduseer word) in die bloed wat u vel en wit van die oë geel kan laat lyk;
- inflammasie van die lewer (hepatitis);
- stuiptrekkings (by mense wat hoë dosisse ADCO-AMOXYCILLIN neem of wat nierprobleme het);
- inflammasie en seerheid van die mond, tong of lippe;
- swart tong wat harig lyk;
- braking;
- sproei (Candida - 'n gisinfeksie van die vagina, mond of velvoue);
- slegte spysvertering;
- duiseligheid;
- hoofpyn;
- 'n toestand van oormatige rusteloosheid;
- tandverkleuring;
- kristalle in urien wat lei tot akute nierbesering;
- inflammasie van buise in die nier.

Frekwensie is onbekend:

- toename in sommige stowwe (ensieme) wat deur die lewer geproduseer word;

- ernstige verlaging in die aantal witbloedselle;
- lae aantal rooibloedselle (hemolitiese anemie);
- lae aantal selle wat betrokke is by bloedstolling.

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

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ADCO-AMOXYCILLIN te verskaf.

U kan dit ook by Adcock Ingram Limited aanmeld deur die volgende e-posadres te gebruik: Adcock.AEReports@adcock.com.

5. Hoe om ADCO-AMOXYCILLIN te bêre

Kapsules en poeier moet:

- gebêre word teen of benede 25 °C.
- beskerm word teen vog.

Hersaamgestelde suspensie:

- Sodra dit hersaamgestel is, moet ADCO-AMOXYCILLIN suspensie binne 7 dae gebruik wanneer gehou word by temperature van hoogstens 25 °C, of moet binne veertien dae gebruik word wanneer verkoel word (2 °C – 8 °C).
- Moenie vries nie.
- Bêre in die oorspronklike houer.
- Hou die houer dig toe.
- Moenie gebruik ná die vervaldatum wat op die etiket / kartonboksie / bottel vermeld word nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.
- Bêre alle medisyne buite bereik van kinders.

6. Inhoud van die verpakking en ander inligting

Wat ADCO-AMOXYCILLIN bevat

- Die aktiewe bestanddeel is:

Amoksisillien

- Die ander bestanddele is:

Kapsules:

Kolloïdale watervrye silika

Magnesiumstearaat

Dop en lyf:

“Brilliant Blue” FCF

Eritrosien BS

Titaandioksied (CI nr. 77891)

“Sunset Yellow”

Natriumlaurielsulfaat

Gelatien

Samestelling van wit ink waarmee kapsule gemerk is

Titaandioksied (CI nr. 77891)

Hars

Isopropielalkohol

Alkohol

“Tween 80”

Suspensies:

Kinolien-geel “supra” (CI nr. 47005)

Suurlemoen droë geursel

Appelkoos droë geursel

Natriummetielhidroksibensoaat

Natriumkarmellose

Natriumsitraat

Kolloïdale watervrye silika

Sukrose

Hoe ADCO-AMOXYCILLIN lyk en die inhoud van die verpakking

Poeiers vir orale suspensie:

Poeier vir orale suspensie is beskikbaar in deursigtige glas en wit HDPE-bottels wat 100 ml of 75 ml van die suspensie verskaf wanneer dit hersaamgestel word.

Kapsules:

Die 250 mg kapsules is verpak in houers van 15, 100, 500 en 1 000 kapsules.

Die 500 mg kapsules is verpak in houers van 15, 100 en 1 000 kapsules, en stulppakke van 15 en 100 kapsules.

Nie alle verpakkingstipes en verpakkingsgroottes word dalk bemark nie.

Houer van Sertifikaat van Registrasie

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Kliëntediens: 0860 ADCOCK / 232625

Hierdie biljet is mees onlangs hersien op

31 Maart 2025

Registrasienommer

ADCO-AMOXYCILLIN 125 mg/5 ml: X/20.1.2/198
ADCO-AMOXYCILLIN 250 mg/5 ml: X/20.1.2/199
ADCO-AMOXYCILLIN 250 mg: X/20.1.2/196
ADCO-AMOXYCILLIN 500 mg: X/20.1.2/197

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