PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

AMDOCIN capsules

Indomethacin 25 mg

Contains sugar: Lactose 95 mg

Read all of this leaflet carefully before you start taking AMDOCIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- AMDOCIN 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 AMDOCIN is and what it is used for

AMDOCIN belongs to a group of medicines called non-steroidal anti-inflammatory medicines or NSAIDs. These work by reducing the body's ability to produce inflammation, which may cause pain and discomfort.

AMDOCIN reduces fever, pain and inflammation.

Your doctor has prescribed AMDOCIN for you because you are suffering from one of the following:

- Rheumatoid arthritis (disease mainly of the joints).
- Osteoarthritis (disease of the joints).
- Ankylosing spondylitis (a form of arthritis which mainly affects the back).
- Muscle and bone disorders (musculoskeletal disorders), such as tendonitis, inflammation of the joints, sprains and strains.
- Pain and swelling in gout (a form of arthritis in which crystals build up in the joints).
- Fever in Hodgkin's disease (a type of cancer).
- Fever (AMDOCIN is used in addition to the primary treatment for a short duration to assist in reducing the fever).
- Pain, inflammation and swelling following orthopaedic surgery or nonsurgical procedures (associated with repositioning bones after dislocation or fracture).

- Pain, inflammation and swelling following dental surgical procedures.

- Period pain.
- Low back pain.
- A disease where the cartilage that serves as a cushion in the joints of the hips deteriorates (degenerative joint disease of the hip).
- Fever, the reduction of symptoms in some conditions which may produce fever (febrile conditions).

2. What you need to know before you take AMDOCIN

Do not take AMDOCIN if you :

- o are hypersensitive (allergic) to indomethacin or any of the other ingredients of AMDOCIN (listed in section 6),
- o have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had episodes of peptic ulcers, stomach bleeding or perforation and bleeding related to previous use of NSAIDs,
- o are taking a medicine called triamterene for swelling and high blood pressure,
- o are taking a medication called diflunisal for pain, swelling, stiffness or joint pain,
- o have polyps in your nose (teardrop-shaped, non-cancerous growths) due to swelling of the area under the skin,
- o have had a history of asthma attacks, hives, or inflammation of the inside of the nose after taking aspirin or other NSAIDs, including AMDOCIN,

- have a history of sensitivity (allergy) that causes swelling of the face and mouth (angioedema) after taking NSAIDs, including AMDOCIN and/or aspirin,
- have heart failure or heart disease and/or cerebrovascular disease, e.g., if you have had a heart attack, stroke, or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages,
- have or have had problems with your blood circulation (peripheral arterial disease),
- have a bleeding disorder,
- have inflammation of the stomach and/or intestines (gastritis, regional enteritis, ulcerative colitis),
- have kidney and/or liver failure,
- are pregnant, do not take NSAIDs such as AMDOCIN, at 30 weeks or later in your pregnancy because these medicines may cause problems in your unborn baby,
- are breastfeeding your baby.

Safety of AMDOCIN in children has not been established.

Warnings and precautions

AMDOCIN may lead to serious heart problems (cardiovascular events), stomach or intestinal problems (gastrointestinal events), or skin reactions (cutaneous reactions) which may lead to death.

Take special care with AMDOCIN if:

- you develop a fever, severe skin rash or skin reaction or any unusual reaction such as facial swelling when starting treatment with AMDOCIN, stop taking AMDOCIN and tell your doctor immediately. These serious events may occur without warning and may be fatal; they include DRESS (Drug Rash with Eosinophilia and Systemic Symptoms), Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN).
- you have, high blood pressure or have a tendency for fluid retention you should only be treated with AMDOCIN after very careful consideration.
- you have now, or ever had, a digestive tract disorder, bleeding in the digestive tract or an episode of stomach (gastric) ulcer (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces).
- bleeding or ulceration of the digestive tract occurs, stop taking AMDOCIN and tell you doctor.
- you have any liver or kidney problems you should be closely monitored by your doctor to ensure that your kidney or liver function does not get worse.
- you have high levels of sugar in the blood (diabetes).
- you smoke or have high levels of bad cholesterol in the blood.
- you are taking a diuretic (water pills) to increase the amount of urine that is excreted.
- you are feeling thirsty, tired, have a dry mouth, feeling dizzy or lightheaded, you may be dehydrated.
- you experience heart palpitations, shortness of breath, chest pain, nausea, or vomiting, you may have high levels of potassium in your blood (hyperkalaemia).
- you have asthma.

- you are epileptic (have seizures), as you may need to stop treatment with AMDOCIN.
- you have Parkinson's disease, as you may need to stop treatment with AMDOCIN.
- you have any psychiatric (mental) disease, talk to your doctor as your treatment may need to be changed.
- you suffer from systemic lupus erythematosus (SLE), an autoimmune disorder, you may have an increased risk of inflammation of the membrane covering the brain (aseptic meningitis).
- you experience dizziness and headaches while taking AMDOCIN you may need to stop taking AMDOCIN as AMDOCIN can aggravate the headaches.
- you have been taking AMDOCIN for a long time and have frequent headaches you should stop taking ARTRHEXIN and tell your doctor.
- you have an infection, because symptoms such as fever and inflammation may be masked. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- you notice any change in your vision, you should see your doctor. If you have rheumatoid arthritis your doctor may want to examine your eyes at intervals during your treatment with AMDOCIN.
- you are elderly or you have previously had stomach ulcers, you have a higher risk of getting side effects, especially related to the stomach. Your doctor should therefore prescribe the lowest dose that gives you sufficient relief. If you experience any unusual stomach problems, you must tell your doctor about it.
- you have a problem with your blood clotting.
- you are anaemic (low red blood count that leaves you feeling very tired).

- you are taking NSAIDs, such as AMDOCIN, at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to be treated with NSAIDs, such as AMDOCIN, for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs, such as AMDOCIN, around 30 weeks of pregnancy or later (see Do not take AMDOCIN).
- you have difficulty becoming pregnant, treatment with AMDOCIN is not recommended.
- you suffer from porphyria.

Children

The safe use of AMDOCIN in children has not been established, children should therefore not take AMDOCIN.

Other medicines and AMDOCIN

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

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

- Anti-coagulants such as warfarin (used to prevent blood clots).
- Other non-steroidal anti-inflammatory medicines (NSAIDs) such as diflunisal or aspirin (used to treat pain and inflammation). Avoid using two or more NSAIDs as this may increase the risk of experiencing adverse effects. Diflunisal should not be taken with AMDOCIN (see Do not take AMDOCIN).
- Antacids, that are used to neutralise stomach acidity and are used to relieve heartburn, indigestion or an upset stomach.

- Sulfonylureas and other medicines used to treat diabetes, as your doctor may need to adjust the dose.
- Probenecid (also used to treat gout)
- Methotrexate (used to treat certain types of cancer or autoimmune disorders).
- Ciclosporin (used to prevent rejection of a transplanted organ).
- Lithium (used to treat mood disorders)
- Diuretics such as furosemide and triamterene and other medicines used to treat high blood pressure. AMDOCIN and triamterene should not be taken together.
- Phenylpropanolamine (used in cold and flu medicines).
- Mifepristone (used to abort pregnancy).
- Medicines used to treat heart disorders (such as digoxin).
- Corticosteroids (used to treat painful or inflammatory conditions or allergies).
- Quinolone antibiotics (used to treat certain bacterial infections).
- Antiretrovirals (used to treat viral infections such as HIV).
- Medicines used to treat leg pain caused by poor blood circulation.
- Medicines to relieve muscle spasms or to relax muscles
- Tacrolimus, medicine that lower the risk of organ rejection after an organ transplant.
- Tiludronic acid, medicine used to treat Paget's disease (broken and deformed bones and pain in the affected area).
- Medicines used to treat depression or psychotic disorders.
- Phenytoin, used to control seizures.
- If you are having blood tests done, make sure that the doctor doing them knows that you are taking AMDOCIN. Misleading results have been seen with patients having a dexamethasone suppression test (DST) while taking AMDOCIN.

AMDOCIN with food and drink

It is recommended that AMDOCIN be taken with food, milk or an antacid.

Pregnancy, breastfeeding and fertility

You should not take AMDOCIN if you are pregnant or breastfeeding your baby

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.

Pregnancy

You must not take AMDOCIN if you are already at 30 weeks or later in your pregnancy. AMDOCIN must not be taken at 30 weeks or later in your pregnancy since it may cause major heart, lung and kidney disorders in the unborn child. If taken at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions delaying the onset of delivery.

Breastfeeding

You should not take AMDOCIN if you are breastfeeding your baby.

Fertility

Taking AMDOCIN may make it more difficult to become pregnant.

Driving and using machines

Since adverse reactions such as dizziness, drowsiness, visual disturbances and headaches have been reported in patients receiving AMDOCIN, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that AMDOCIN does not adversely affect your ability to do so safely.

It is not always possible to predict to what extent AMDOCIN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which AMDOCIN affects you (see section 4).

AMDOCIN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AMDOCIN.

3. How to take AMDOCIN

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

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

Use the lowest effective dose for the shortest possible duration of treatment.

The usual dose of AMDOCIN is 25 mg two to three times per day taken with food. Do not take more than 200 mg of AMDOCIN per day.

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

Do not stop treatment early because your doctor will monitor your recovery and advise you when to stop treatment.

If you have the impression that the effect of AMDOCIN is too strong or too weak, tell your doctor or pharmacist.

If you take more AMDOCIN than you should

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

If you take high doses of AMDOCIN, you may experience side effects such as headache, nausea, vomiting, indigestion, pain in the upper abdomen, ulceration and/or gastrointestinal bleeding, diarrhoea, disorientation, unusually excited, coma, drowsiness, dizziness, ringing in the ears, fainting, restlessness.

In the event of overdose your doctor will monitor your symptoms and treat you according to your condition.

If you forget to take AMDOCIN

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

If you forget to take AMDOCIN, take it as soon as you remember. If it is nearly time for your next dose, just carry on with the next dose as normal.

If you stop taking AMDOCIN

You should take AMDOCIN for as long as your doctor tells you to. You should not stop taking it without your doctor's advice.

4. Possible side effects

AMDOCIN can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering and/or peeling of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).
- eruption of lesions on the skin known as erythema multiforme,
- fever, flu-like symptoms, a painful red rash, may include purplish spots that spreads and blisters follow where the top part of the skin dies and peels off known as toxic epidermal necrolysis (TEN), or Drug Rash with Eosinophilia and System Symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to AMDOCIN. 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 in breathing especially if you suffer from, or have a history of asthma or allergic disease (bronchospasm), coughing, feeling tired, wheezing (pulmonary oedema),

- swelling of legs, ankles and feet, feeling tired and weak, shortness of breath, lack of appetite, swelling of stomach, rapid or irregular/abnormal heartbeat, pain in the chest, neck, back or arms (heart failure),
- infection in the soft tissue that spreads rapidly and eats away at the flesh (necrotising fasciitis),
- increased thirst, increased need to urinate, tiredness, dry mouth, blurry vision, slow healing of cuts or sores (these may be symptoms of diabetes),
- sudden or unusual fatigue, weight loss, frequent infections and easy bleeding or bruising (these may be symptoms of leukaemia),
- pale skin, tiredness, fever, sore throat and mouth, small red spots on the skin, bruising or prolonged bleeding after injury, severe chills, mouth ulcers, headache, shortness of breath and dizziness, these may be symptoms of blood disorders,
- heart palpitations, shortness of breath or stomach pain and diarrhoea, chest pain, heart palpitations or irregular, fast or fluttering heartbeat, muscle weakness or numbness in limbs, nausea and vomiting, these may be signs of high levels of potassium in your blood (hyperkalaemia),
- feeling severely depressed or confused including thinking about suicide, seeing or hearing things that are not there (hallucinations), mental disorders; including a loss of personal identity (psychosis, psychiatric disturbances, depersonalisation),
- pain with eye movement (optic neuritis), temporary vision loss, cloudy or milky appearance in the eye,

- nausea, vomiting blood, tenderness when touching the stomach (pancreatitis),
- vomiting any blood or dark particles that look like coffee grounds (haematemesis),
- passing blood in your faeces (stools/motions),
- diarrhoea (particularly if severe), weight loss, fever and/or stomach pain (regional ileitis),
- inflammation of the bowel (Crohn's disease),
- inflammation (swelling and redness) inside the mouth (ulcerative stomatitis),
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems known as jaundice,
- intense itching, dark urine, light coloured stools, pain in the upper right portion of your abdomen (gall stones),
- convulsions, coma, involuntary muscle movement, neck pain or stiffness, headache,
- altered mental status,
- deafness,
- shortness of breath, decreased urine output, drowsiness, fluid retention causing swelling in your legs, ankles or feet, confusion, nausea, chest pain or pressure (kidney failure)
- pink-red blotches and/or bumps on the skin (erythema), inflammation of the walls of small blood vessels (angiitis),

- redness, sudden swelling in the leg or arm with tenderness and feeling of increased warmth (thrombophlebitis),
- loss of sensation, numbness, tingling and pricking sensations (peripheral neuropathy),
- sudden and rapid fall in 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:

- Headache, dizziness, light headedness, anxiety,
- increased sensitivity to sun and ultraviolet light (photosensitivity),
- increased levels of urea in the blood. These changes in blood composition are normally be picked up in urine or blood tests.

Less frequent side effects:

- Drowsiness,
- difficulty sleeping (insomnia),
- sensation that things around you are moving (vertigo),
- tiredness (including feeling unwell and listlessness),
- bleeding from the nose (epistaxis),
- loss of appetite (anorexia),
- redness and peeling of the skin over large areas of the body (exfoliative dermatitis),
- speech problems (dysarthria),
- blurred vision, changes in vision, pain in the eye (orbital and peri-orbital pain),

- tiny round, brown-purple spots due to bleeding under the skin (petechiae),
- a discoloration of the skin resulting from bleeding underneath, typically caused by bruising (ecchymosis),
- sugar in the urine, confirmed by laboratory test or dipstick test (glycosuria), urinating more frequently.

Side effects with an unknown frequency:

- Flushing,
- ringing in the ears (tinnitus), hearing disturbances,
- indigestion or heartburn (dyspepsia),
- worsening of epilepsy and parkinsonism symptoms (symptoms that mimic those of Parkinson's disease such as tremor or abnormal movements). If these side effects are severe you may need to stop treatment with AMDOCIN. You should talk to your doctor,
- pins and needles (paraesthesia),
- visual field changes
- dry cough, fever, general ill feeling, rapid breathing, shortness of breath, wheezing (pulmonary eosinophilia),
- high blood pressure (hypertension), low blood pressure (hypotension),
- hair loss (alopecia),
- sweating,
- aggravation of psoriasis (inflamed patches get bigger and spread faster),
- muscle weakness, accelerated breakdown of cartilage in the joints,
- blood in the urine (haematuria)

- vaginal bleeding,
- breast changes including enlargement and tenderness in men and women (gynaecomastia),
- weight gain,
- fluid retention (oedema).
- 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: https://www.sahpra.org.za/health-products-vigilance/

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

5. How to store AMDOCIN

Store all medicines out of reach of children. Store at or below 25 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

Do not store in a bathroom.

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 AMDOCIN contains

The active substance is: 25 mg of indomethacin.

The other ingredients are: gelatin, Lactose, maize starch, microcrystalline cellulose, sodium starch glycolate,

Hard gelatin capsule, with a yellow cap and body:

Quinoline yellow, sunset yellow, titanium dioxide.

What AMDOCIN looks like and contents of the pack

AMDOCIN capsules are yellow gelatin capsules containing white to off-white powder.

AMDOCIN capsules are packed:
Aluminium foil/PVC film blister strip of 15 capsules and a package insert in a printed carton.

4 Aluminium foil/PVC film blister strip of 21 capsules and a package insert in a printed carton.

Bottles containing 100, 500 and 1 000 capsules.

Not all pack sizes may be marketed

Holder of Certificate of Registration

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Access to the corresponding professional information:

Follow the link for the corresponding Professional Information for AMDOCIN:

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

alternatively please scan the QR code below:

PASIËNTINLIGTINGBILJET

SKEDULERINGSTATUS **S3**

AMDOCIN Kapsules

Indometasien 25 mg

Bevat suiker: Laktose 95 mg

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

- Hou hierdie biljet. U mag dit moontlik weer wil lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegster of ander gesondheidsorgvoorsiener.
- AMDOCIN 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 AMDOCIN is en waarvoor dit gebruik word

AMDOCIN behoort aan ‘n groep medisynes wat genoem word nie-steroïed anti-inflammatoriese medisynes of NSAIMs. Dit werk deur die liggaam se vermoë om inflammasie te veroorsaak te verminder, wat pyn en ongemak kan veroorsaak.

AMDOCIN verminder koors, pyn en inflammasie.

U dokter het AMDOCIN vir u voorgeskryf omdat u een van die volgende het:

- Rumatoïede artritis (siekte hoofsaaklik van die gewrigte).
- Osteoartritis (siekte van die ledemate).
- Ankiloserende spondilitis (‘n vorm van artritis wat hoofsaaklik die rug beïnvloed).
- Spier- en beenafwykings (muskuloskeletale afwykings), soos tendonitis, inflammasie van die gewrigte, verrekking en swigting.
- Pyn en swelsel met jig (‘n vorm van artritis waar kristalle opbou in die gewrigte).
- Koors in Hodgkin se siekte (‘n tipe kanker).
- Koors (AMDOCIN word gebruik addisioneel tot die primêre behandeling vir ‘n kort tydperk deur te help om die koors af te bring).
- Pyn, inflammasie en swelsel na ortopediese sjirurgie of nie-sjirurgiese prosedures (geassosieer met herplasing van bene na dislokasie van ‘n fraktuur).
- Pyn, inflammasie en swelsel na dentale sjirurgiese prosedures.
- Maandstonde pyn.
- Lae rugpyn.

- ‘n Siekte waar die kraakbeen wat dien as ‘n kussing in die gewrigte van die heupe agteruitgaan (degeneratiewe gewrigsiekte van die heup).
- Koors, die vermindering van simptome in sommige toestande wat koors kan veroorsaak (febriele toestande).

2. Wat u behoort te weet voordat u AMDOCIN neem

Moenie AMDOCIN neem nie indien u:

- hipersensitief (allergies) is vir indometasien of enige van die ander bestanddele van AMDOCIN (aangedui in afdeling 6),
- ‘n peptiese ulkus het (ulkus in u maag of duodenum) of bloeding in u maag, of indien u episodes of peptiese ulkusse gehad het, maag-bloeding of perforasie en bloeding verwant aan vorige gebruik van NSAIMs,
- ‘n medisyne neem wat genoem word triamtereen vir swelsel en hoë bloeddruk,
- ‘n medisyne neem wat genoem word diflunisal vir pyn, swelsel, styfheid of gewrigspyn,
- poliepe in u neus het (traandruppel-vormige, nie-kankeragtige groeisels) weens die swelsel van die area onder die vel,
- ‘n geskiedenis het van asma-aanvalle, huiduitslag of inflammasie aan die binnekant van die neus nadat u aspirien of ander NSAIMs geneem het, insluitend AMDOCIN,
- ‘n geskiedenis het van sensitiwiteit (allergie) wat opswel van die gesig en mond veroorsaak (angioedeem) nadat u NSAIMs geneem het, insluitend AMDOCIN en/of aspirien,

- ‘n hartversaking of hartsiekte het en/of serebrovaskulêre siekte, bv. indien u ‘n hartaanval gehad het, beroerte, of blokkasies na bloedvate na die hart of brein of ‘n operasie vir opklaar of omweg-blokkerings,
- probleme het of gehad het met u bloedsirkulasie (perifere arteriële siekte),
- ‘n bloedingsafwyking,
- inflammasie van die maag en/of derms (gastritis, streekenteritis, ulseratiewe kolitis),
- nier- en/of lewerversaking het,
- swanger is, moenie NSAIMs neem soos AMDOCIN nie, by 30 weke of later in u swangerskap omdat hierdie medisynes probleme kan veroorsaak in u ongebore baba,
- u baba borsvoed.

Veiligheid van AMDOCIN in kinders is nog nie vasgestel nie.

Waarskuwings en voorsorgmaatreëls

AMDOCIN kan ernstige hartprobleme tot gevolg hê (kardiovaskulêre voorvalle), maag of intestinale probleme (gastroïntestinale voorvalle), of velreaksies (kutaneuse reaksies) wat sterfte tot gevolg kan hê.

Neem spesiale sorg met AMDOCIN indien:

- u koors ontwikkel, ernstige veluitslag of velreaksie of enige ongewone reaksie soos opswel van u gesig wanneer u met die behandeling van AMDOCIN begin, staak die gebruik van AMDOCIN en vertel u dokter onmiddellik. Hierdie ernstige voorvalle kan voorkom sonder waarskuwing en kan noodlottig wees; dit sluit in

DRESS (Medisyne Uitslag met Eosinofilie en Sistemiese Simptome), Stevens-Johnson se sindroom en toksiese epidermale nekrolise (TEN).

- u hoë bloeddruk het, of ‘n tendens het vir vloeistof-retensie, moet u slegs behandel word met AMDOCIN na omsigtige oorweging.
- u nou, of ooit, ‘n spysverteringskanaalafwyking gehad het, bloeding in die spysverteringskanaal of ‘n episode van maag (gastriese) ulkus (dit kan insluit bloed in braking, bloeding wanneer maag geledig word, vars bloed in die fesies).
- bloeding of ulserasie van die spysverteringskanaal voorkom, staak die gebruik van AMDOCIN en raadpleeg u dokter.
- u enige lewer- of nierprobleme het, moet u noukeurig gemonitor word deur u dokter om seker te maak dat u nier- of lewerfunksie nie agteruitgaan nie.
- u hoë vlakke suiker in die bloed het (diabetes).
- u rook of hoë vlakke van slegte cholesterol in die bloed het.
- u ‘n diuretika neem (waterpille) om die hoeveelheid uriene wat uitgeskei word te verhoog.
- u dors voel, moeg, ‘n droë mond het, duiseligheid ondervind of lighoogdigheid, kan u moontlik gedehidreer wees.
- u hartklopping ondervind, asemtekort, borspyn, naarheid, of braking, kan u moontlik hoë vlakke van kalium in u bloed hê (hiperkalemie).
- u asma het.
- u epileptiese aanvalle kry (aanval van siekte), omdat u moontlik behandeling met AMDOCIN moet staak.
- u Parkinson se siekte het, omdat u moontlik u behandeling met AMDOCIN moet staak.

- u enige psigiatriese (geestes) siekte het, raadpleeg u dokter omdat u behandeling moontlik verander moet word.
- u sistemiese lupus erythematosus (SLE) het, ‘n outo-immuun siekte, kan u ‘n verhoogde risiko hê van inflammasie van die membraan oor die brein (aseptiese meningitis).
- u duiseligheid en hoofpyn ondervind terwyl u AMDOCIN neem, moet u moontlik die gebruik van AMDOCIN staak, omdat AMDOCIN die hoofpyne erger kan maak.
- u AMDOCIN vir ‘n lang tyd geneem het en dikwels hoofpyn kry, moet u AMDOCIN staak en u dokter raadpleeg.
- u ‘n infeksie het, omdat simptome soos koors en inflammasie gemaskeer mag wees. Indien u hierdie medisyne neem terwyl u ‘n infeksie het en u simptome van die infeksie aanhou of erger word, raadpleeg u dokter dadelik.
- u enige verandering agterkom in u visie, gaan sien u dokter onmiddellik. Indien u rumatoïede artritis het, sal u dokter moontlik u oë ondersoek by gereëlde intervalle gedurende u behandeling met AMDOCIN.
- u bejaard is of indien u voorheen maagsere gehad het, het u ‘n hoër risiko om newe-effekte te ontwikkel, verwant aan die maag. U dokter behoort dus die laagste dosis voor te skryf wat u voldoende verligting kan gee. Indien u enige ongewone maagprobleme ondervind, moet u dit aan u dokter meld.
- u ‘n probleem het met u bloedstolling.
- u anemies is (lae rooi bloedtelling wat veroorsaak dat u baie moeg voel).
- u NSAIMs neem, soos AMDOCIN, by ongeveer 20 weke swangerskap of later, kan dit u ongebore baba benadeel. Indien u behandel moet word met NSAIMs, soos AMDOCIN, vir meer as 2 dae wanneer u tussen 20 en 30 weke swanger is,

moet u gesondheidsorgvoorsiener moontlik die hoeveelheid vloeistof in u baarmoeder rondom u baba monitor. Moenie NSAIMs neem, soos AMDOCIN, rondom 30 weke van swangerskap of later nie (sien Moenie AMDOCIN neem nie).

- u probleme het om swanger te word, word behandeling met AMDOCIN nie aanbeveel nie.
- u porfirie het.

Kinders

Die veilige gebruik van AMDOCIN by kinders is nog nie vasgestel nie, dus moet kinders nie AMDOCIN gebruik nie.

Ander medisynes en AMDOCIN

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

Vertel u dokter indien u enige van die volgende neem:

- Anti-koagulante soos warfarien (word gebruik vir voorkoming van bloedklonte).
- Ander nie-steroïed anti-inflammatoriese medisynes (NSAIMs) soos diflunisal of aspirien (word gebruik vir behandeling van pyn en inflammasie). Vermy die gebruik van twee of meer NSAIMs omdat dit die risiko van ongunstige reaksies kan laat toeneem. Diflunisal moet nie geneem te word met AMDOCIN nie (sien Moenie AMDOCIN neem nie).
- Teensuurmiddels, wat gebruik word om maagsure te neutraliseer and wat gebruik word vir die verligting van sooibrand, slegte spysvertering of ‘n ongekrapte maag.

- Sulfonielureums en ander medisynes wat gebruik word vir die behandeling van diabetes, omdat u dokter moontlik die dosering moet aanpas.
- Probenesied (word ook gebruik om jig te behandel).
- Metotreksaat (word gebruik by die behandeling van sekere tipes van kanker of outo-immuun siektes).
- Siklosporien (word gebruik vir voorkoming van die verwerping van ‘n oorgeplante orgaan).
- Litium (word gebruik by behandeling van gemoedsafwykings).
- Diuretiese middels soos furosemied en triamtereen en ander medisynes wat gebruik word by die behandeling van hoë bloeddruk. AMDOCIN en triamtereen moet nie saam gebruik word nie.
- Fenielpropanolamien (word gebruik in verkoue en griep medisynes).
- Mifepristoon (word gebruik vir aborsie met swangerskap).
- Medisynes wat gebruik word om hartsiektes te behandel (soos digoksien).
- Kortikosteroïede (word gebruik by die behandeling van pynlike of inflammatoriese toestande of allergieë).
- Kinolone antibiotika (word gebruik by die behandeling van sekere bakteriële infeksies).
- Antiretrovirale middels (word gebruik by die behandeling van virale infeksies soos MIV).
- Medisynes wat gebruik word by die behandeling van beenpyn wat veroorsaak word deur swak bloedsirkulasie.
- Medisynes vir die verligting van spierspasma of om spiere te ontspan.
- Takrolimus, medisyne wat die risiko of orgaan-verwerping na ‘n orgaanoorplanting laat afneem.

- Tiludroniese suur, medisyne wat gebruik word by die behandeling van Paget se siekte (gebreekte en misvormde bene en pyn in die areas geaffekteer).
- Medisynes wat gebruik word by die behandeling van depressie of psigotiese afwykings.
- Fenitoïen, word gebruik by die beheer van siekte-aanvalle.
- Indien u bloedtoetse laat doen, maak seker dat die dokter wat dit doen weet dat u AMDOCIN neem. Misleidende resultate is waargeneem by pasiënte wat deksametasoon onderdrukkingtoets (DST) gehad het, terwyl hulle AMDOCIN neem.

AMDOCIN met voedsel en drankies

Dit word aanbeveel dat AMDOCIN geneem word met voedsel, melk of ‘n teensuurmiddel.

Swangerskap, borsvoeding en fertiliteit

U moet nie AMDOCIN neem indien u swanger is of u baba borsvoed nie.

Indien u swanger is of borsvoed, dink dat u swanger mag wees of ‘n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgvoorsiener vir advies voordat u hierdie medisyne neem.

Swangerskap

U moet nie AMDOCIN neem indien u alreeds by 30 weke of later in u swangerskap is nie. AMDOCIN moet nie geneem word by 30 weke of later in u swangerskap nie omdat dit major hart-, long- en nierafwykings in die ongebore kind kan veroorsaak.

Indien geneem aan die einde van die swangerskap, kan dit bloedingstendense in beide die moeder en kind veroorsaak en die sterkte van uteriene kontraksies laat afneem wat die aanvang van baring kan vertraag.

Borsvoeding

U moet nie AMDOCIN neem indien u die baba borsvoed nie.

Fertiliteit

Die neem van AMDOCIN kan dit moontlik moeiliker maak om swanger te word.

Bestuur en gebruik van masjinerie

Omdat ongunstige reaksies soos duiseligheid, lomerigheid, visuele versteurings en hoofpyne gerapporteer is by pasiënte wat AMDOCIN ontvang het, moet u nie bestuur, masjinerie gebruik of enige take verrig wat konsentrasie benodig nie, totdat u seker is dat AMDOCIN u nie ongunstig beïnvloed om dit veilig te doen nie.

Dit is nie altyd moontlik om te voorspel tot watter mate AMDOCIN kan inmeng met u daaglikse aktiwiteite nie. U moet seker maak dat u nie deelneem aan die boonste aktiwiteite nie totdat u seker is tot watter mate AMDOCIN u beïnvloed (sien afdeling 4).

AMDOCIN bevat laktose

Indien u deur u dokter ingelig is dat u ‘n intoleransie het vir sommige suikers, kontak u dokter voordat u AMDOCIN neem.

3. Hoe om AMDOCIN te neem

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

Neem AMDOCIN altyd presies soos u dokter of apteker aanbeveel het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Gebruik die laagste effektiewe dosis vir die kortste moontlike tydperk van behandeling.

Die gewone dosis van AMDOCIN is 25 mg twee tot drie keer per dag met voedsel. Moenie meer as 200 mg AMDOCIN per dag neem nie.

U dokter sal u inlig hoe lank u behandeling met AMDOCIN sal duur.

Moenie behandeling te vroeg staak nie omdat u dokter u toestand sal monitor en u sal inlig wanneer om die behandeling te staak.

Indien u die indruk het dat die effek van AMDOCIN te sterk of te swak is, vertel u dokter of apteker.

Indien u meer AMDOCIN geneem het as wat u moes

Ingeval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of vergiftingskontrole sentrum.

Indien u hoë doserings AMDOCIN neem, kan u newe-effekte kry soos hoofpyn, naarheid, braking, slegte spysvertering, pyn in die boonste abdomen, ulserasie en/of gastroïntestinale bloeding, diarree, disoriëntasie, ongewone opgewondenheid, koma, lomerigheid, duiseligheid, gelui in die ore, floute, rusteloosheid.

Ingeval van oordosering sal u dokter u simptome monitor en u behandel volgens u toestand.

Indien u vergeet het om AMDOCIN te neem

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

Indien u vergeet het om AMDOCIN te neem, neem dit so gou as wat u onthou. Indien dit amper tyd is vir u volgende dosis, gaan aan met die volgende dosis soos normaalweg.

Indien u die gebruik van AMDOCIN staak

U moet AMDOCIN neem vir so lank as wat u dokter u aanbeveel het. U moet nie die gebruik staak sonder u dokter se advies nie.

4. Moontlike newe-effekte

AMDOCIN kan newe-effekte hê.

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

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

- Opswel van die hande, voete, enkels, gesig, lippe en mond of keel, wat kan verooorsaak dat u probleme het om te sluk of asem te haal,
- uitslag of jeuk,
- floute,
- blasie-vorming en/of afskilfering van die vel, mond, oë en genitale areas, omdat dit kan wees weens ‘n ernstige allergiese reaksie wat bekend staan as Stevens-Johnson se Sindroom (SJS).
- erupsie van letsels op die vel wat bekend staan as erythema multiforme,
- koors, griepagtige simptome, ‘n pynlike rooi uitslag, wat pers kolle kan insluit, wat versprei en blasies vorm waar die boonste deel van die vel afsterf en afdop, wat bekend staan as toksiese epidermale nekrolise (TEN) of Medisyne Uitslag met Esinofilie en Sistemiese Simptome (DRESS).

Hierdie is almal baie ernstige newe-effekte. Indien u dit het, het u moontlik ‘n ernstige reaksie gehad met AMDOCIN. U kan moontlik dringende mediese sorg benodig of hospitalisering.

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

- Probleme met asemhaling, veral indien u ‘n geskiedenis het van asma of allergiese siekte (brongospasma), hoes, gevoel van moegheid, asemfluit (pulmonêre edeem),
- opswel van bene, enkels en voete, gevoel van moegheid en swakheid, asemtekort, verlies van aptyt, opswel van maag, vinnige of ongereëlde/abnormale hartklop, pyn in die bors, nek, rug of arms (hartversaking),
- infeksie in die sagte weefsel wat vinnig versprei en die vleis weg eet (nekrotiese fassitis),
- verhoogde dors,verhoogde gevoel om te urineer, uitputting, droë mond, dowwe visie, stadige herstel van snye en sere (hierdie kan simptome wees van diabetes),
- skielike of ongewone uitputting, massaverlies, dikwelse infeksies en maklike bloeding of kneusing (hierdie kan simptome wees van leukemie),
- bleek vel, uitputting, koors, seer keel en mond, klein rooi spikkels op die vel, kneusing of verlengde bloeding na besering, ernstige koue rillings, mond-ulkusse, hoofpyn, tekort aan asem en duiseligheid, hierdie kan simptome wees van bloedafwykings,
- hartkloppings, asemtekort of maagpyn en diarree, borspyn, hartkloppings of ongereëlde, vinnige of fladderende hartklop, spierswakheid of gevoelloosheid in ledemate, naarheid en braking, hierdie kan tekens wees van hoë vlakke van kalium in u bloed (hiperkalemie),

- gevoel van ernstige depressie of verwarring, insluitend gedagte aan selfdood, sien of hoor van dinge wat nie daar is nie (hallusinasies), geestesafwykings; insluitend ‘n verlies van persoonlike identiteit (psigose, psigiatriese versteurings, verontpersoonliking),
- pyn met oogbeweging (optiese neuritis), tydelike visie verlies, wolkerige of melkerige voorkoms in die oog,
- naarheid, braking van bloed, teerheid wanneer aan die maag geraak word (pankreatitis),
- braking van enige bloed of donker deeltjies wat soos koffie moer lyk (hematemese),
- passeer van bloed in u fesies (ontlasting/stoelgang),
- diarree (veral indien ernstig), massaverlies, koors en/of maagpyn (gebied ileïtis),
- inflammasie van die maag (Crohn se siekte),
- inflammasie (swelsel en rooiheid) in die mond (ulseratiewe stomatitis),
- geel word van die vel en oë, donker uriene, en uitputting, wat tekens kan wees van lewerprobleme, wat bekend is as geelsug,
- intense jeuk, donker uriene, lig-gekleurde stoelgang, pyn in die boonste regterkant van u abdomen (galstene),
- konvulsies, koma, onwillekeurige spierbeweging, nekpyn of styfheid, hoofpyn
- veranderde geestes-status,
- doofheid,

- asemtekort, afname in uitset van uriene, lomerigheid, vloeistof retensie wat veroorsaak dat u bene, enkels of voete opswel, verwarring, naarheid, borspyn of druk (nierversaking),
- ligrooi-rooi kolle en/of knoppe op die vel (eriteem), inflammasie van die wande van klein bloedvate (angïtis),
- rooiheid, skielike opswel van die been of arm met teerheid en gevoel van toename in warmheid (tromboflebitis),
- verlies van sensasie, gevoelloosheid, tinteling en prikkel-sensasies (perifere neuropatie),
- skielike of vinnige val in bloeddruk.

Hierdie is almal baie ernstige newe-effekte. U kan moontlik dringende mediese sorg benodig.
Vertel u dokter indien u enige van die volgende opmerk:
Dikwelse newe-effekte:

- Hoofpyn, duiseligheid, lighoofdigheid, angstigheid,
- toename in sensitiwiteit tot son en ultraviolet lig (fotosensitiwiteit),
- verhoogde vlakke van ureum in die bloed. Hierdie veranderinge in bloedsamestelling kan gewoonlik opgetel word in uriene of bloedtoetse.

Minder dikwelse newe-effekte:

- Lomerigheid,
- slaap probleme (insomnie),
- sensasie dat goed om u beweeg (vertigo),
- uitputting (insluitend gevoel van siek wees en lusteloosheid),
- bloeding uit die neus (epistaksis),
- verlies van aptyt (anorekie),

- rooiheid en afdop van die vel oor groot areas van die liggaam (eksfoliatiewe dermatitis).
- spraakprobleme (disartrie),
- dowwe visie, veranderinge in visie, pyn in die oog (orbitale en peri-orbitale pyn),
- klein ronde, bruin-pers kolle weens bloeding onder die vel (puntbloeding),
- ‘n verkleuring van die vel as gevolg van bloeding aan die onderkant, tipies veroorsaak deur kneusing (eggimose),
- suiker in die uriene, bevestig deur laboratorium-toets of meetstok-toets (glikosurie), meer dikwelse urinering.

Newe-effekte met ‘n onbekende frekwensie:

- Blosing,
- gelui in die ore (tinnitus), gehoorversteurings,
- slegte spysvertering of sooibrand (dispepsie),
- agteruitgang van epilepsie en parkinsonisme simptome (simptome wat die mimiek van Parkinson se siekte soos tremor of abnormale bewegings). Indien hierdie newe-effekte ernstig is, moet u moontlik die behandeling met AMDOCIN staak. U moet u dokter raadpleeg.
- naalde en spelde (parestesie),
- visuele gebied-veranderinge,
- droë hoes, koors, algemene siek gevoel, vinnige asemhaling, asemhalingstekort, asemfluit (pulmonêre esinofilie),
- hoë bloeddruk (hipertensie), lae bloeddruk (hipotensie),
- haarverlies (alopesie),

- sweet,
- agteruitgang van psoriase (ontsteekte kolle wat groter word en vinniger versprei),
- spierswakheid, versnelde afbraak van kraakbeen in die gewrigte,
- bloed in die uriene (hematurie),
- vaginale bloeding,
- borsveranderinge, insluitend vergroting en teerheid by mans en vrouens, (ginekomastie),
- massatoename,
- vloeistof-retensie (edeem).
- Indien u enige newe-effekte opmerk wat nie gemeld word in hierdie biljet nie, stel asseblief u dokter of apteker in kennis daarvan.

Rapporteer van newe-effekte

Indien u newe-effekte kry, raadpleeg u dokter, apteker of verpleegster, U kan hierdie newe-effekte rapporteer aan: SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Deur newe-effelte te rapporteer, kan u help om meer inligting te voorsien omtrent die veiligheid van AMDOCIN.

5. Hoe om AMDOCIN te berg

Berg alle medisynes buite die bereik van kinders, Berg by of benede 25 °C.

Beskerm teen lig en vog.

Hou in die oorspronklike verpakking totdat dit benodig word vir gebruik.

Moenie in die badkamer bêre nie.

Moenie gebruik na die vervaldatum wat op die etiket gemeld word nie.

Neem alle ongebruikte medisyne terug na u apteker.

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

6. Inhoud van die pakkie en ander inligting

Wat AMDOCIN bevat

Die aktiewe substans is: 25 mg of indometasien.

Die ander bestanddele is: gelatien, laktose, mieliestysel, mikrokristallyn sellulose, natriumstysel glikolaat.

Harde gelatien kapsule, met ‘n geel doppie en romp:

Kinolien geel, “sunset” geel, titaniumdioksied.

Hoe AMDOCIN lyk en inhoud van die pakkie

AMDOCIN kapsules is geel gelatien kapsules, bevattende wit tot naaswit poeier.

AMDOCIN kapsules word verpak:
Aluminiumfoelie/PVC film stolpstrokie met 15 kapsules en ‘n voubiljet in ‘n gedrukte karton.

4 Aluminiumfoelie/PVC film stolpstrokie met 21 kapsules en ‘n voubiljet in ‘n gedrukte karton.

Bottels bevattende 100, 500 en 1 000 kapsules.

Nie alle pakgroottes sal bemark word nie.

Houer van Sertifikaat van Registrasie

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Toegang tot die ooreenstemmende professionele inligting:

Volg die skakel vir die ooreenstemmende Professionele Inligting vir AMDOCIN:

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

alternatief skandeer asseblief die QR kode hieronder: