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
2. What you need to know before you take AMDOCIN
3. How to take AMDOCI
4. Possible side effects
5. How to store AMDOCIN
6. Contents of the pack and other information

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 :

- are hypersensitive (allergic) to indomethacin or any of the other ingredients of AMDOCIN (listed in section 6),
- 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,
- are taking a medicine called triamterene for swelling and high blood pressure,
- are taking a medication called diflunisal for pain, swelling, stiffness or joint pain,
- have polyps in your nose (teardrop-shaped, non-cancerous growths) due to swelling of the area under the skin,
- 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,

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