SCHEDULING STATUS S3

NOVACAM 7,5 mg (tablets)

NOVACAM 15 mg (tablets)

Meloxicam

Each NOVACAM 7,5 mg tablet contains 23,50 mg lactose monohydrate

Each NOVACAM 15 mg tablet contains 20,00 mg lactose monohydrate

Please read this leaflet carefully before you are given NOVACAM

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

1. What NOVACAM is and what it is used for

Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which are used to treat swelling, stiffness, inflammation (red, hot, painful, swollen area), pain and fever.

NOVACAM tablets are used to relieve pain and inflammation of diseases of the joints (arthritis), the spinal column (ankylosing spondylitis) and for symptomatic relief of acute episodes of sciatica (pain in the hip nerve) in patients over 12 years of age.

2. What you need to know before you take NOVACAM

Do not take NOVACAM:

- If you are hypersensitive (allergic) to meloxicam or any of the other ingredients of NOVACAM (listed in section 6)
- if you are under the age of 12 years
- if you are pregnant, planning to become pregnant or if you are breastfeeding (see “pregnancy and lactation”)
- if you are allergic to aspirin or other anti-inflammatory medicines
- if you have ever developed signs of wheezing (asthma), nasal polyps (nasal obstruction due to swellings in the lining of your nose) along with a runny nose, swelling of the skin or urticaria (nettle rash) when taking aspirin or any other anti-inflammatory medicines
- if you have or have ever had a gastrointestinal ulcer (ulcer of the stomach or intestines), or perforation
- if you have active inflammatory bowel disease (Crohn’s disease or ulcerative colitis)
- if you have serious liver disease
- if you have serious kidney disease and are not undergoing dialysis
- If you have ever suffered from bleeding in the stomach or intestines (gastrointestinal bleeding), including bleeding caused by aspirin or any other anti- inflammatory medicines (NSAIDs) or bleeding in the brain (cerebrovascular bleeding) or any other kind of bleeding disorders

- if you have a chronic condition in which the heart doesn't pump blood as well as it should (severe congestive heart failure)
- for the treatment of pain before of after surgery of the bloodvessels which supply the heart with blood.
- surgery which diverts blood around narrowed or clogged parts of the major arteries to improve blood flow and oxygen supply to the heart (bypass graft (CABG) surgery)

Warnings and precautions

NOVACAM may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you are taking NOVACAM for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Special care should be taken with NOVACAM

Tell your doctor or healthcare provider:

- if you have a history of oesophagitis (inflammation of the gullet) or gastritis (inflammation of the stomach) or any other gastrointestinal disease e.g. ulcerative colitis, Crohn's disease, part of your stomach had moved up into your chest (hiatus hernia), heartburn (gastro-oesophageal Reflux disease), an abnormality with the blood vessels in the gastrointestinal tract (angiodysplasia). Gastrointestinal bleeding or ulcer can occur at any time during treatment with NOVACAM, with or without warning symptoms
- if you have high blood pressure
- if you have heart, liver or kidney disease
- if you have diabetes
- if you are elderly as side-effects may occur more frequently.

- if you have hypovolaemia (reduced blood volume) which may occur if you have serious blood loss or burns, surgery or low fluid intake
- if you have ever been diagnosed with high potassium levels in the blood
- if you use an intrauterine device (IUD) as NOVACAM may reduce the contraceptive effectiveness of the device
- if you develop any skin rash (reddish target-like spots or circular patches often with central blisters on the trunk), sores on the linings, of nose, mouth etc., or other signs of allergy.
- if you have sodium, potassium or water retention.

NOVACAM is not appropriate if you require immediate relief from acute pain.

Children

NOVACAM tablets should NOT be used in children under 12 years of age.

Other medicine and NOVACAM

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

NOVACAM can interfere with other medicines such as:

- other non-steroidal anti-inflammatory drugs (NSAIDs) including aspirin can intensify stomach or bowel side effects
- corticosteroids, as these may increase the possibility of bleeding from the gut
- medicines which prevent blood clotting, e.g. warfarin or heparin may cause enhanced risk of bleeding
- medicines which break down blood clots (thrombolytics and antiplatelet medicine) increases the risk of gastrointestinal bleeding
- selective serotonin re-uptake inhibitors (used in the treatment of depression), as these may increase the possibility of bleeding from the gut
- lithium (a medicine mainly used to treat mood disorders) may cause increase the concentration of lithium in your blood

- methotrexate (a medicine mainly used to treat tumours or severe uncontrolled skin conditions (psoriasis) and active rheumatoid arthritis) may cause serious toxicity
- any diuretic medicine ("water tablets") – your doctor may monitor your kidney function and potassium levels in your blood if you are taking diuretics
- medicines used to treat high blood pressure and heart failure (ace inhibitors, beta-blockers and angiotensin II receptor antagonists) may have a reduced blood pressure lowering effect
- probenecid (used to manage gout) may increase the effect of NOVACAM
- cholestyramine (mainly used to lower cholesterol levels) may lower the effect of NOVACAM
- ciclosporin (a medicine often used to treat rejection after organ transplants, and in immune diseases) increase the risk of kidney damage
- tacrolimus (a medicine often used to treat rejection after organ transplants and in immune diseases) increase the risk of kidney damage
- oral anti-diabetic medicines can intensify stomach or bowel side effects
- pemetrexed (a medicine used to treat certain types of cancer) can intensify stomach and bowel side effects.

NOVACAM with food and alcohol

Simultaneous intake of alcohol increases the risk of bleeding.

Pregnancy, breastfeeding and fertility

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

NOVACAM should not be used during pregnancy or while breastfeeding or if. You think you may be pregnant or are planning to have a baby.

Use of NOVACAM during the early stages of your pregnancy can increase the risk of miscarriage, defects of the heart of the baby or gastroschisis, which is a condition where the baby's intestines are found outside of the baby's body.
The use of NOVACAM during the third trimester can result in prolonged labour as well as prolonged bleeding time for the mother as well as the newborn baby. The baby can also be exposed to the kidneys not working properly (renal dysfunction) or damage to the heart muscle (cardiopulmonary toxicity).

Driving and using machines

Do not drive or operate machinery until you know how NOVACAM tablets affect you. It may make you feel lightheaded, dizzy or drowsy and may cause blurred vision. If these tablets affect you in this way, DO NOT drive or operate machinery.

NOVACAM contains lactose

NOVACAM 7,5 mg tablets contain 47 mg lactose per maximum recommended daily dose. Patients with the rare hereditary conditions of galactose intolerance, e.g. galactosaemia, Lapp-lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take NOVACAM.

NOVACAM 15 mg tablets contain 20 mg lactose per maximum recommended daily dose. Patients with rare hereditary conditions of galactose intolerance, e.g. galactosaemia, Lapplactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take NOVACAM.

NOVACAM contains lactose monohydrate (a type of sugar) which may have an effect on the control of your blood sugar of patients with diabetes mellitus.

3. How to take NOVACAM

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

Always take NOVACAM exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual recommended dosage is 7,5 mg or 15 mg.

The doctor will determine your dose based your condition, your age, how your kidney and liver work.

Your doctor will aim to use the lowest effective dose for as short a time as is necessary to try and reduce the risk of side effects.

Do NOT exceed the recommended maximum dose of 15 mg a day.

Take NOVACAM with a drink of water or other liquid and with food.

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

If you take more NOVACAM than you should

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

Symptoms following acute NOVACAM overdose are usually limited to lack of energy, drowsiness, nausea, vomiting and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur.

Severe poisoning may result in high blood pressure, kidneys lose the ability to remove waste and balance fluids (acute kidney failure), liver gets damaged and cannot functions as it should (liver dysfunction), slow and ineffective breathing (respiratory depression), coma, seizures (convulsions), Loss of sufficient blood flow to maintain consciousness (cardiovascular collapse) and sudden, unexpected loss of heart function, breathing and consciousness (cardiac arrest). Severe, potentially life-threatening allergic reactions (anaphylactoid reactions) have been reported with therapeutic ingestion of NOVACAM and may occur following an overdose.

If you forget to take NOVACAM

If you forget to take NOVACAM tablets, take it as soon as you remember unless it is nearly

218 time for your next dose, skip the missed dose.

If you stop taking NOVACAM

Do not stop taking NOVACAM without first checking with your doctor.

4. POSSIBLE SIDE EFFECTS

NOVACAM may have side effects.

Not all side effects reported for NOVACAM are included in this leaflet.

Should your general health worsen of if you experience any untoward effects while receiving NOVACAM, please inform your doctor, pharmacist or other healthcare provider for advice.

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

- symptoms of an allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching and feeling unwell.
- appearance of skin rash or any lesion of the mucous surface (for example, blistering or ulceration along the inside of the mouth).
- NOVACAM may be associated with an increased risk of heart attack (“myocardial infarction”) or stroke. Symptoms may include chest pain, shortness of breath, weakness and slurring of speech.

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

- asthma (difficulty in breathing) - seen in people who are allergic to aspirin or other nonsteroidal anti-inflammatory medicines
- stomach or intestinal ulcer

- inflammation of the large bowel (diarrhoea usually with bloody or black-coloured stools and mucous, stomach pain and fever)
- soreness of the gullet
- vomiting blood or material that looks like coffee grounds
- severe, persistent abdominal pain
- severe skin reaction which may be associated with painful red areas, large blisters and
- peeling of layers of skin with fever and chills, aching muscles and generally feeling unwell, or severe blistering and bleeding in mucous membranes (lips, eyes, mouth, nose and genitals), urticaria (nettle rash)
- cardiac failure (disease of the heart with shortness of breath and swelling of face, feet or
- lower legs due to fluid build-up
- unusual fast or irregular heartbeat or palpitations
- abnormality of white blood cell or platelet numbers, unusual bleeding or bruising, sore
- throat, fever and chills
- liver disease (with nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching,
- yellowing of the skin and eyes, and dark coloured urine)
- kidney disease where you pass little or no urine – other symptoms include drowsiness,
- nausea, vomiting and breathlessness
- confusion and disorientation, mood changes

Tell your doctor if you notice any of the following:

Frequent:

- gastrointestinal symptoms such as indigestion (dyspepsia), feeling sick (nausea) or being sick (vomiting), abdominal pain or loose stools (diarrhoea), flatulence (wind)
- headache

Less frequent:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- asthma (difficulty in breathing) in persons allergic to aspirin or other non-steroidal anti-inflammatory medicines
- gastritis (a stomach problem which may result in pain,
- vomiting blood, and blood in the bowel motions), burping
- gastrointestinal bleeding (causing offensive, tar-coloured stools or vomiting blood)
- inflammation or soreness of the mouth or gullet, stomach or intestinal ulcer, colitis (inflammation of the colon or Crohn's disease), which may be worsened bleeding
- anaemia, changes in blood count test results (including low white cell count), unusual bleeding or bruising, sore throat, fever and chills
- skin reactions which may be severe, skin rash, itching, which may be accompanied by yellowing of the whites of the eyes and skin and darkened urine
- palpitations, heart failure
- general oedema (swelling of face, feet or lower legs)
- increase in blood pressure (high blood pressure)
- flushing
- abnormalities in tests of liver function
- abnormalities in tests of kidney function, any changes in urination
- vertigo (dizziness or spinning sensation), tinnitus (noises in the ear)
- dizziness, somnolence (sleepiness or drowsiness), insomnia (sleeplessness), nightmares
- altered mood, confusion and disorientation
- visual disturbances including blurred vision, conjunctivitis (discharge with itching of the eyes)
- increased sun sensitivity
- delayed ovulation and infertility in females
- hypokalaemia (low blood potassium levels)

- renal tubular acidosis (improper removing of acids from your blood into the urine)

NOVACAM, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of NOVACAM 50.

5. How to store NOVACAM

Store all medicines out of reach of children.

Store at or below 25 °C, in a cool dry place.

Keep in the outer container until required for use.

Do not use after the expiry date stated on the label/carton.

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 NOVACAM contains

The active ingredient is meloxicam per tablet.

The other ingredients are:

Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, pregelatinised maize starch, sodium citrate

What NOVACAM looks like and contents of the pack

NOVACAM 7,5 mg tablets:

Light yellow, round, uncoated tablet with score line between 'F' and '1' debossed on one side and plain on the other side.

NOVACAM 15 mg tablets:

Light yellow, round, uncoated tablet with score line between 'F' and '2' debossed on one side and plain on the other side.

Pack size: 30 tablets in a printed cardboard carton containing 3 blister packs (white opaque PVC film coated with/PVdC and aluminium foil) of 10 tablets each.

REGISTRATION NUMBERS

NOVACAM 7,5 mg: 51/3.1/0074

NOVACAM 15 mg: 51/3.1/0075

HOLDER OF THE CERTIFICATE OF REGISTRATION

Unimed Healthcare (ty) Ltd

Corner Birch Road & Bluegum Avenue,

Anchorville,

Lenasia

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