Approved Patient Information Leaflet for Medicines for Human Use:

MELOXICAM 7,5 mg AUSTELL Tablets

MELOXICAM 15 mg AUSTELL Tablets

SCHEDULING STATUS

S3

MELOXICAM 7,5 mg AUSTELL Tablets

MELOXICAM 15 mg AUSTELL Tablets

Meloxicam

Contains sugar (lactose monohydrate)

Each **MELOXICAM 7,5 mg AUSTELL** tablet contains 18,75 mg lactose monohydrate.

Each **MELOXICAM 15 mg AUSTELL** tablet contains 37,50 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking MELOXICAM AUSTELL

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

6. Contents of the pack and other information

1. What MELOXICAM AUSTELL is and what it is used for

MELOXICAM AUSTELL contains the active substance meloxicam.

Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines are usually used to treat inflammation, swelling, stiffness, pain and fever.

MELOXICAM AUSTELL is used in patients aged 12 years and older for the following:

- to relieve symptoms of arthritis such as joint pain and inflammation,
- ankylosing spondylitis (an inflammatory disease that can cause some of the vertebrae in your spine to fuse together),
- acute episodes of sciatica (pain in the hip nerve).

2. What you need to know before you take MELOXICAM AUSTELL

Do not take MELOXICAM AUSTELL

- if you are hypersensitive (allergic) to meloxicam or any of the other ingredients of MELOXICAM AUSTELL (listed in section 6),
- if you are allergic to aspirin or other anti-inflammatory medicines,
- if you have ever suffered from the following:
    - wheezing (asthma), chest tightness, breathlessness,
    - nasal blockage due to swellings in the lining of your nose (nasal polyps) along with a runny nose,
    - skin rash (urticaria),
    - sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioedema),

- if you have or have recently had a gastrointestinal ulcer (ulcer of the stomach or intestines) or holes (perforation) in your stomach or intestines,
- if you have active inflammatory bowel disease (Crohn's disease or ulcerative colitis),
- if you have severe liver disease,
- if you have serious kidney disease and are not undergoing dialysis,
- if you have any kind of established general bleeding disorder or have ever suffered from gastrointestinal bleeding (bleeding in the stomach or intestines) or cerebrovascular bleeding (bleeding in the brain),
- if you have heart failure, (i.e. when your heart inadequately pumps blood through the body),
- if you have ever suffered from gastrointestinal bleeding (bleeding in the stomach or intestines) or perforation after taking aspirin or any other anti-inflammatory medicines,
- if you are under the age of 12 years,
- if you are pregnant, planning to become pregnant or if you are breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with MELOXICAM AUSTELL:

- if you are younger than 12 years old,
- if you have high blood pressure or heart disease as you may retain fluid and increase your risk of heart attack or stroke,
- if you are elderly, side effects may happen more often, especially bleeding in the stomach and intestines, ulceration or perforation (which may be fatal), and you should discuss this with your health care provider,

- as gastrointestinal bleeding or ulcer can occur at any time during treatment with MELOXICAM AUSTELL, with or without warning symptoms. Tell your health care provider if you have a history of gastrointestinal disease or have ever suffered from gastrointestinal disease e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia (abnormality with blood vessels in the gastrointestinal tract),
- if you develop any skin rash, flu-like symptoms followed by a red or purple rash that spreads and forms blisters (a condition known as Stevens-Johnson syndrome), or severe skin peeling or blistering (toxic epidermal necrolysis),
- if you are taking diuretics (water tablets), you may retain more salt, potassium and water in your body (swollen hands and feet) and this may cause or worsen heart failure or high blood pressure,
- if you have kidney disease (such as nephrotic syndrome, glomerulonephritis, papillary necrosis),
- if you have hypovolaemia (reduced blood volume) which may occur after surgery or low fluid intake,
- if you have liver disease,
- if you have an infection as MELOXICAM AUSTELL may mask the symptoms of an infection,
- if you have been told by your health care provider you have an intolerance to some sugars as this product contains lactose,
- if you are a woman who uses an intrauterine contraceptive device (IUD) usually known as a coil, as the contraceptive may not work so well,
- if you are pregnant as MELOXICAM AUSTELL may cause kidney problems in your unborn baby. Use of MELOXICAM AUSTELL in the last trimester can also cause problems with the baby's heart/ blood pressure,

- if you present with a fever, rash, swollen lymph nodes, facial swelling, symptoms of a viral infection, as you may be experiencing a drug reaction with MELOXICAM AUSTELL. This can also result in high levels of eosinophils in the blood and abnormal blood results. Other symptoms may include infection of the kidney, liver, heart muscle. Please stop treatment with MELOXICAM AUSTELL if you experience these symptoms and speak to your health care provider.

Children and adolescents

MELOXICAM AUSTELL is not suitable for children and adolescents below 12 years of age.

Other medicines and MELOXICAM AUSTELL

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

In particular, please tell your doctor or pharmacist if you are taking/have taken, or are using any of the following:

- other non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin,
- corticosteroids (medicine used against inflammation or allergic reactions) as this may increase the risk of ulcers or bleeding,
- medicines which prevent blood clotting (anticoagulants), e.g. warfarin, heparin,
- medicines which break down blood clots (thrombolytics),
- anti-platelet medicines, e.g. clopidrogel, as well as selective serotonin re-uptake inhibitors (used in the treatment of depression),
- lithium (a medicine used to treat mood disorders),
- methotrexate (a medicine mainly used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis),

- if you are a woman who uses an intrauterine contraceptive device (IUD) usually known as a coil as the contraceptive may not work so well,
- diuretic medicines ("water tablets") – your health care provider may monitor your kidney function if you are taking diuretics,
- medicines used to treat high blood pressure e.g. beta-blockers,
- probenecid (used to manage gout),
- cholestyramine (mainly used to lower cholesterol levels),
- cyclosporin (a medicine often used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome),
- tacrolimus (a medicine often used after organ transplants),
- oral anti-diabetic medicines.

MELOXICAM AUSTELL with food and drink

Simultaneous intake of alcohol increases the risk of bleeding.

Pregnancy, breastfeeding and fertility

You should not use MELOXICAM AUSTELL during pregnancy, breastfeeding or trying to fall pregnant.

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

Driving and using machines

Visual disturbances, including blurred visions, drowsiness and vertigo (sense of spinning) may occur with MELOXICAM AUSTELL. If affected do not drive or use machinery.

MELOXICAM AUSTELL contains lactose monohydrate

If you are lactose intolerant, do not take MELOXICAM AUSTELL If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MELOXICAM AUSTELL.

3. How to take MELOXICAM AUSTELL

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

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

The usual dose is:

Rheumatoid arthritis

One 15 mg tablet once per day or two 7,5 mg tablets once per day.

This may be reduced to one 7,5 mg tablet once per day, depending on the response.

Ankylosing spondylitis

One 15 mg tablet once per day or two 7,5 mg tablets once per day. This may be reduced to one 7,5 mg tablet once per day, depending on the response.

Osteoarthritis

One 7,5 mg tablet once per day. This may be increased to one 15 mg tablet once per day or two 7,5 mg tablets once per day, if necessary.

Episodes of acute sciatica

One 7,5 mg tablet once per day. This may be increased to one 15 mg tablet once per day or two 7,5 mg tablets once per day, if no improvement is seen.

Elderly population

Start with one 7,5 mg tablet once per day.

Patients with kidney problems

One 7,5 mg tablet once per day. Do not exceed this dose.

Do not exceed the recommended maximum dose of 15 mg] MELOXICAM AUSTELL per day.

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

Method of administration

The tablets should be swallowed with water or other fluid with a meal.

If you take more MELOXICAM AUSTELL than you should

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

Symptoms following MELOXICAM AUSTELL overdose, are usually limited to lack of energy (lethargy), drowsiness, feeling sick (nausea) and being sick (vomiting), pain in the area of the stomach (epigastric pain). You may suffer from bleeding of the stomach or intestines (gastrointestinal bleeding).

These symptoms generally get better when you stop taking MELOXICAM AUSTELL.

The standard treatment of gastric emptying and general symptomatic and supportive treatment should be used as there is no known antidote. It is reported that cholestyramine may accelerate the elimination of MELOXICAM AUSTELL.

If you forget to take MELOXICAM AUSTELL

Take your dose when you remember. Do not take a double dose to make up for the missed dose.

4. Possible side effects

MELOXICAM AUSTELL can have side effects.

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

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

- Any allergic (hypersensitivity) reactions, which may appear in the form of:
  - skin reactions, such as itching (pruritus), blistering or peeling of the skin, which can be potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), lesions of soft tissues (mucosal lesions) or erythema multiforme. Erythema multiforme is a serious allergic skin reaction causing spots, red welts or purple or blistered areas. It can also affect the mouth, eyes and other moist body surfaces.
  - swelling of skin or mucosa, such as swelling around the eyes, face and lips, mouth or throat, possibly making breathing difficult, swollen ankles or legs (oedema of the lower limbs),
  - shortness of breath or asthma attack.

These are all very serious side effects. If you have them, you may have had a serious reaction to MELOXICAM AUSTELL. 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 non-steroidal anti-inflammatory drugs,
- severe abdominal pain,
- inflammation of the large bowel (diarrhoea usually with bloody or black-coloured stools and mucous, stomach pain and fever),
- tar-coloured stool due to bleeding in the digestive tract (melaena),
- vomiting of blood (haematemesis),
- 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, feeling unwell, or sever blistering and bleeding in mucous membranes (lips, eyes, mouth, nose and genitals),
- heart failure (with shortness of breath and swelling of the face, lower legs and feet due to fluid build-up),
- unusual fast or irregular heart-beat of palpitations,
- abnormality of blood results, platelet numbers, unusual bleeding or bruising, sore throat, fever and chills,
- liver disease (with nausea, vomiting, loss of appetite, 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, disorientation and mood changes.

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, light headedness, feeling drowsy,
- swelling of the face, legs or lower limbs (oedema),
- nausea, vomiting, stomach pain, constipation, diarrhoea, gas in stomach (flatulence), haematemesis (vomiting blood), melaena (dark stools),
- gastrointestinal adverse events such as indigestion (dyspepsia), feeling sick (nausea) and being sick (vomiting), abdominal pain, constipation, flatulence, loose stools (diarrhoea).

Less frequent side effects:

- anaemia (reduction of the concentration of the red blood pigment haemoglobin), change in blood count rest results (including low white cell count, platelets),
- immediate allergic (hypersensitivity) reactions, tightness of the chest, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing of breathing,
- change in mood, nightmares,
- dizziness, inability to sleep, sleeping too much,
- disturbances in vision, blurred vision, conjunctivitis (discharge with itching of the eyes),
- vertigo (dizziness or spinning sensation), tinnitus (noises in the ear),
- palpitations,
- increased blood pressure, flushing,

- bronchospasm (narrowing of the airways), asthma,
- bleeding from the gastrointestinal tract, ulcers, inflammation of the oesophagus (tube which runs from the throat to the stomach), stomatitis (painful swelling and sores inside the mouth), inflammation of the stomach,
- abnormal liver function tests, inflammation of the liver,
- severe skin adverse reactions, itching, rash, hives, life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme),
- abnormalities in tests of kidney function, sodium and water retention, increased potassium, acute kidney failure,
- inflammation of the stomach (gastritis),
- bleeding of the digestive tract.

Side effects with frequency unknown:

- life-threatening allergic reactions (anaphylaxis),
- confusion, disorientation,
- heart failure,
- pancreatitis (inflammation of the pancreas),
- photosensitivity reactions, drug reaction with fever, rash, swollen lymph nodes, swelling of the face and high levels of disease-fighting white blood cells, known as eosinophils (DRESS),
- female infertility (difficulty to fall pregnant), delayed ovulation.

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 health care provider. 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 MELOXICAM AUSTELL**.**

5. How to store MELOXICAM AUSTELL

Store all medicines out of reach of children.

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

Do not use this medicine after the expiry date which is printed on the 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 MELOXICAM AUSTELL contains

- The active substance is meloxicam.
- The other ingredients are colloidal silicon dioxide, crospovidone (polyplasdone XL), lactose monohydrate, magnesium stearate, microcrystalline cellulose PH 102, povidone K25, sodium citrate dihydrate.

What MELOXICAM AUSTELL looks like and contents of the pack

MELOXICAM AUSTELL tablets are light yellow, round, flat tablets, scored on one side.

MELOXICAM AUSTELL tablets are light yellow, round, flat tablets, scored on one side and embossed 'M15' on the other side.

MELOXICAM AUSTELL tablets are available in transparent PVC/PVDC -Aluminium foil blister packs of 30 tablets, packed in a dark green outer cardboard carton.

MELOXICAM AUSTELL tablets are available in transparent PVC/PVDC -Aluminium foil blister packs of 10 and 30 tablets, packed in a dark green outer cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG, 2193

Tel: +27 11 611 1400 or +27 860 287 835

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