Approved Professional Information for Medicines for Human Use:

MELOXICAM 7,5 mg AUSTELL Tablets

MELOXICAM 15 mg AUSTELL Tablets

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

MELOXICAM 7,5 mg AUSTELL tablets

MELOXICAM 15 mg AUSTELL tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each MELOXICAM 7,5 mg AUSTELL tablet contains 7,5 mg meloxicam.

Each MELOXICAM 15 mg AUSTELL tablet contains 15 mg 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.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

MELOXICAM 7,5 mg AUSTELL tablets are light yellow, round, flat tablets, scored on one side.

MELOXICAM 15 mg AUSTELL tablets are light yellow, round, flat tablets, scored on one side and embossed ‘M15’ on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MELOXICAM AUSTELL is indicated for:

- symptomatic treatment of rheumatoid arthritis
- symptomatic treatment of painful osteoarthritis
- symptomatic treatment of ankylosing spondylitis
- symptomatic treatment of episodes of acute sciatica.

4.2 Posology and method of administration

Posology

Adults

The maximum recommended daily dose of MELOXICAM AUSTELL is 15 mg.

As the potential for adverse reactions increases with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used.

Combined administration

The total daily dosage of MELOXICAM AUSTELL administered should not exceed 15 mg.

Special populations

Rheumatoid arthritis

15 mg/day. According to the therapeutic response, the dose may be reduced to 7,5 mg/day.

Ankylosing spondylitis

15 mg/day. According to the therapeutic response, the dose may be reduced to 7,5 mg/day.

Osteoarthritis

7,5 mg/day. If necessary, the dose may be increased to 15 mg/day.

Episodes of acute sciatica:

7,5 mg/day. If necessary, in the absence of improvement, the dose may be increased to 15 mg/day.

Elderly population

In patients with increased risks of adverse reactions (e.g. the elderly), start treatment at the dose of 7,5 mg/day.

Renal impairment

In dialysis patients with severe renal failure the dose should not exceed 7,5 mg/day.

Paediatric population

As a dosage for use in children has yet to be established, MELOXICAM AUSTELL should not be used in children aged less than 12 years.

Method of administration

MELOXICAM AUSTELL tablets should be swallowed with water or other fluid in conjunction with food.

4.3 CONTRAINDICATIONS

MELOXICAM AUSTELL is contraindicated in patients with hypersensitivity to the active substance or any of the other ingredients of MELOXICAM AUSTELL (see section 6.1).

There is a potential for cross sensitivity to aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs).

MELOXICAM AUSTELL should not be given to patients who have developed signs of asthma, nasal polyps, angioedema or urticaria following the administration of acetylsalicylic acid or other NSAIDs.

Further contraindications for the use of MELOXICAM AUSTELL are:

- active or recent gastrointestinal ulceration/perforation

- active inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- severe hepatic insufficiency
- non-dialysed severe renal insufficiency
- overt gastrointestinal bleeding, recent cerebrovascular bleeding or established systemic bleeding disorders
- uncontrolled heart failure
- history of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs
- children under 12 years.

MELOXICAM AUSTELL is contraindicated during pregnancy (see section 4.4 and 4.6).
MELOXICAM AUSTELL is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
In case of rare hereditary conditions that may be incompatible with an excipient of MELOXICAM AUSTELL (see section 4.4), the use of MELOXICAM AUSTELL is contraindicated.

4.4 Special warnings and precautions for use

Children under the age of 12 years as safety and efficacy have not been established.

Cardiovascular effects

Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with MELOXICAM AUSTELL therapy.
MELOXICAM AUSTELL may increase the risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Elderly

The elderly have an increased frequency of adverse reactions to NSAIDs including MELOXICAM AUSTELL, especially gastrointestinal bleeding and perforation (PUBs), which may be fatal.

Frail or debilitated patients may tolerate side-effects less well and such patients should be carefully supervised. Caution should be used in the treatment of elderly patients who are more likely to be suffering from impaired renal, hepatic or cardiac function.

Gastrointestinal effects

Gastrointestinal bleeding, ulceration or perforation (PUBs), potentially fatal, can occur at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events.

The risk of PUBs is higher with increasing doses of MELOXICAM AUSTELL in patients with a history of ulcers, and the elderly.

When gastrointestinal bleeding or ulceration occurs in patients receiving MELOXICAM AUSTELL, treatment with MELOXICAM AUSTELL should be stopped.

MELOXICAM AUSTELL should be given with caution to patients with a history of gastrointestinal disease (e.g., ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia), as the condition may be exacerbated (see section 4.3).

Skin effects

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of MELOXICAM AUSTELL. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. MELOXICAM AUSTELL should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Sodium, potassium and water retention

Induction of sodium, potassium and water retention and interference with natriuretic effects of diuretics may occur with MELOXICAM AUSTELL. Cardiac failure or hypertension may be precipitated or exacerbated in susceptible patients as a result. For patients at risk, clinical monitoring is recommended.

Renal effects

MELOXICAM AUSTELL inhibits the synthesis of renal prostaglandins which play a supportive role in the maintenance of renal perfusion in patients whose renal blood flow and blood volume are decreased. In these patients, administration of MELOXICAM AUSTELL may precipitate overt renal decompensation which is typically followed by recovery to pre-treatment state upon discontinuation of therapy.

Patients at greatest risk of such a reaction are elderly individuals, dehydrated patients, those with congestive heart failure, liver cirrhosis, nephrotic syndrome and overt renal disease, those receiving concomitant treatment with a diuretic, ACE inhibitor or angiotensin-II receptor antagonist or those having undergone major surgical procedures which led to hypovolaemia. In such patients the volume of

diuresis and the renal function should be carefully monitored at the beginning of therapy.

No dose reduction is required in patients with mild or moderate renal impairment (i.e. in patients with a creatinine clearance of greater than 25 mL/min) (see section 4.2).

MELOXICAM AUSTELL may cause interstitial nephritis, glomerulonephritis, papillary necrosis and the nephrotic syndrome.

Hepatic effects

Occasional elevations of serum transaminases or other indicators of liver function have been reported. In most cases these have been small and transient increases above the normal range. If the abnormality is significant or persistent, MELOXICAM AUSTELL should be stopped and follow up tests carried out.

No dose reduction is required in patients with clinically stable liver cirrhosis.

Infections

MELOXICAM AUSTELL may mask symptoms of an underlying infectious disease.

For relevant medicine interactions that require particular attention, see section 4.5.

Risk of foetal renal dysfunction and foetal ductus arteriosus

The use of nonsteroidal anti-inflammatory drugs (NSAIDs) around 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment.

Oligohydramnios is often, but not always, reversable with treatment discontinuation. Complications of prolonged oligohydramnios may include limb contractures and delayed lung maturation (see section 4.3 and 4.6). Invasive procedures such as exchange transfusion or dialysis may be required.

If NSAID treatment is deemed necessary between 20 to 30 weeks of pregnancy, limit use to the lowest effective dose and shortest duration possible.

Consider ultrasound monitoring of amniotic fluid if NSAID treatment extends beyond 48 hours. Discontinue the NSAID if oligohydramnios occurs and follow up according to clinical practice (see section 4.3 and 4.6).

Avoid prescribing NSAIDs at 30 weeks and later in pregnancy because of the additional risk of premature closure of the foetal ductus arteriosus (see section 4.6).

Risk of drug reaction with eosinophilia and systemic symptoms (DRESS)

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as MELOXICAM AUSTELL. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis. Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, discontinue MELOXICAM AUSTELL and evaluate the patient immediately.

Excipient lactose monohydrate

MELOXICAM AUSTELL tablets contain lactose monohydrate.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

Other prostaglandin synthetase inhibitors (PSIs) including NSAIDs, glucocorticoids and salicylates (acetylsalicylic acid)

Co-administration of prostaglandin synthetase inhibitors (PSIs) may increase the risk of gastrointestinal ulcers and bleeding, via a synergistic effect and is not recommended. The concomitant use of MELOXICAM AUSTELL with other NSAIDs is not recommended.

Concomitant administration of aspirin to healthy volunteers reportedly led to an increase in the AUC and Cmax of MELOXICAM AUSTELL. The clinical significance of this interaction is not known.

Oral anticoagulants, antiplatelet medicines, systemically administered heparin, thrombolytics and selective serotonin reuptake inhibitors (SSRIs)

An increased risk of bleeding via inhibition of platelet function. If such a co-prescription cannot be avoided, close monitoring is required.

Lithium

MELOXICAM AUSTELL has been reported to increase plasma lithium levels (via decreased renal excretion of lithium), which may reach toxic values.

The concomitant use of lithium and MELOXICAM AUSTELL is not recommended. If this combination appears necessary, lithium plasma concentrations should be monitored carefully during the initiation, adjustment and withdrawal of MELOXICAM AUSTELL treatment.

Methotrexate

MELOXICAM AUSTELL can reduce the tubular secretion of methotrexate thereby increasing the plasma concentrations of methotrexate. For this reason, for patients on high dosages of methotrexate (more than 15 mg/week) the concomitant use of MELOXICAM AUSTELL is not recommended. The risk of an interaction between MELOXICAM AUSTELL and methotrexate should be considered, also in patients on low dosage of methotrexate, especially in patients with impaired renal function. When combination treatment is necessary, blood cell count and the renal function should be monitored. When MELOXICAM AUSTELL and methotrexate are given within 3 days of each other, the plasma level of methotrexate may increase and cause increased toxicity. Although the pharmacokinetics of methotrexate (15 mg/week) were not relevantly affected by concomitant MELOXICAM AUSTELL treatment, it should be considered that the haematological toxicity of methotrexate can be amplified by treatment with MELOXICAM AUSTELL

Contraception

MELOXICAM AUSTELL has been reported to decrease the efficacy of intrauterine devices.

Diuretics

Treatment with MELOXICAM AUSTELL is associated with the potential for acute renal insufficiency in patients who are dehydrated. Patients receiving MELOXICAM AUSTELL and diuretics should be adequately hydrated and be monitored for renal function prior to initiating treatment.

Antihypertensives (e.g., β-blockers, ACE-inhibitors, vasodilators, diuretics)

A reduced effect of antihypertensive medicines by inhibition of vasodilating prostaglandins has been reported during treatment with MELOXICAM AUSTELL.

MELOXICAM AUSTELL and angiotensin-II receptor antagonists as well as ACE inhibitors exert a synergistic effect on the decrease of glomerular filtration. In patients with pre-existing renal impairment this may lead to acute renal failure.

Probenecid

Concomitant treatment with probenecid leads to reduced excretion and thereby increased effects of MELOXICAM AUSTELL.

Cholestyramine

Binds meloxicam in the gastrointestinal tract leading to a faster elimination of MELOXICAM AUSTELL

Cyclosporin

Nephrotoxicity of cyclosporin may be enhanced by MELOXICAM AUSTELL via renal prostaglandin mediated effects. During combined treatment, renal function should be assessed regularly.

Tacrolimus

Should not be combined with MELOXICAM AUSTELL.

Cytochrome (CYP) P450 enzymes

MELOXICAM AUSTELL is eliminated almost entirely by hepatic metabolism, of which approximately two thirds are mediated by cytochrome (CYP) P450 enzymes (CYP 2C9 major

pathway and CYP 3A4 minor pathway) and one third by other pathways, such as peroxidase oxidation. The potential for a pharmacokinetic interaction should be taken into account when MELOXICAM AUSTELL and medicines known to inhibit, or to be metabolised by CYP 2C9 and/or CYP 3A4 are administered concurrently.

Antacids, cimetidine, digoxin and furosemide

No relevant pharmacokinetic interactions were detected with respect to the concomitant administration of antacids, cimetidine, digoxin and furosemide.

Oral anti-diabetics

Interactions with oral anti-diabetics cannot be excluded.

Alcohol

Simultaneous administration of alcohol and MELOXICAM AUSTELL increases the risk of bleeding.

4.6 Fertility, pregnancy and lactation

Pregnancy

MELOXICAM AUSTELL is contraindicated during pregnancy.

Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or the embryo-foetal development. Reported data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastrochisis after use of a prostaglandin synthesis inhibitor in early pregnancy.

The use of NSAIDS, such as MELOXICAM AUSTELL used at 20 weeks gestation or later may cause serious kidney problems in an unborn baby.
Foetal renal dysfunction can lead to oligohydramnios due to the low levels of amnionic fluid. Complications of prolonged oligohydramnios may include limb contractures and delayed lung

maturation (see section 4.2 and 4.4).

Use of MELOXICAM AUSTELL during the third trimester of pregnancy is contraindicated.

During the third trimester of pregnancy, prostaglandin synthesis inhibition may expose the foetus to:

- cardiopulmonary toxicity (with premature closure of the foetal ductus arteriosus *in utero* and possible pulmonary hypertension of the newborn)
- renal dysfunction, which may progress to renal failure with oligohydramnios.

may expose the mother and the neonate, at the end of pregnancy, to:

- prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Breastfeeding

NSAIDs such as MELOXICAM AUSTELL, are known to pass into mother's milk. Administration of MELOXICAM AUSTELL is therefore contraindicated in women who are breastfeeding.

Fertility

The use of MELOXICAM AUSTELL may impair fertility and is not recommended in women attempting to conceive. Therefore, in women who have difficulties conceiving, or who are undergoing investigation of infertility, withdrawal of MELOXICAM AUSTELL should be considered.

4.7 Effects on ability to drive and use machines

Patients should not operate machinery or drive a vehicle if they experience drowsiness, blurred vision or any other central nervous system effect.

4.8 Undesirable effects

a)Summary of the safety profile

Reported clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

The frequencies of adverse drug reactions are listed below.

b) Tabulated list of adverse reactions

System Organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Not known**
Blood and lymphatic system disorders		Anaemia Abnormal blood count (including differential white cell count), leukopenia, neutropenia, thrombocytopenia	

		Agranulocytosis	
Immune system disorders		Hypersensitivity reactions including anaphylaxis, angioedema and bronchospasm (especially if patient is aspirin sensitive and has asthma and/or nasal polyps). MELOXICAM AUSTELL should be withdrawn immediately.	Anaphylactic reaction, anaphylactoid reaction
Psychiatric disorders		Altered mood, nightmares	Confusion, disorientation
Nervous system disorders	Headache, light headedness, drowsiness	Dizziness, insomnia, somnolence	
Eye disorders		Visual disturbances including blurred vision, conjunctivitis	
Ear and labyrinth disorders		Vertigo, tinnitus	
Cardiac disorders	Oedema	Palpitations	Cardiac failure*

Vascular disorders		Increased blood pressure, flushing	
Respiratory, thoracic and mediastinal disorders		Bronchospasm Asthma in individuals allergic to acetylsalicylic acid or other NSAIDs	
Gastrointestinal disorders	Dyspepsia, nausea, vomiting, abdominal pain, constipation, flatulence, diarrhoea, melaena, haematemesis	Occult or macroscopic gastrointestinal haemorrhage**, stomatitis, gastritis, eructation, induction or exacerbation of colitis, gastroduodenal ulcer**, oesophagitis, gastrointestinal bleeding, perforation or ulceration**	Pancreatitis
Hepatobiliary disorders		Liver function disorder (e.g. raised transaminases or bilirubin) Hepatitis	
Skin and subcutaneous tissue disorders		Angioedema, pruritus, rash	Photosensitivity Drug reaction with eosinophilia and

		Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), flushing, urticaria Bullous dermatoses, erythema multiforme Severe cutaneous adverse reactions (SCARs)	systemic symptoms (DRESS) (see section 4.4)
Renal and urinary disorders		Nephrotic syndrome, glomerulonephritis, interstitial nephritis, papillary necrosis, Sodium and water retention, hyperkalaemia, abnormal renal function test (increased serum creatinine and/or serum urea), Acute renal failure in particular in patients with risk factors	

Reproductive system and breast disorders			Female infertility, Delayed ovulation
General disorders and administration site conditions		Oedema including oedema of the lower limbs	

* Cardiac failure has been reported in association with NSAID treatment

** Gastrointestinal haemorrhage, ulceration or perforation may sometimes be severe and potentially fatal, especially in the elderly (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions 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

4.9 Overdose

Symptoms

Symptoms following MELOXICAM AUSTELL overdose are usually limited to lethargy, drowsiness, nausea, vomiting and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Severe poisoning may result in hypertension, acute renal failure, hepatic dysfunction, respiratory depression, coma, convulsions, cardiovascular collapse and cardiac arrest. Anaphylactoid reactions have been reported with therapeutic ingestion of MELOXICAM AUSTELL and may occur following an overdose.

Treatment

Treatment is symptomatic and supportive as there is no known antidote.

Absorption should be reduced by:

- Activated charcoal if patient presents 1 to 2 hours after overdose.
- Cholestyramine 4 g oral dose given three times a day.
- Gastric lavage if within 1 hour of overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 3.1 Antirheumatics (anti-inflammatory medicines)

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic medicines, non-steroids; oxicams

ATC Code: M01AC06

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the enolic acid class, which has shown anti-inflammatory, analgesic and antipyretic properties.

A common mechanism for the above effects may exist in the ability of meloxicam to inhibit the biosynthesis of prostaglandins, known mediators of inflammation.

A selective inhibition of cyclo-oxygenase-2 (COX-2) relative to cyclo-oxygenase-1 (COX-1) by meloxicam has been demonstrated.

COX-2 inhibition relates to the anti-inflammatory effects of NSAIDs whereas inhibition of constitutive COX-1 is thought to be responsible for gastric and renal side-effects.

5.2 Pharmacokinetic properties

Absorption

Meloxicam is well absorbed from the gastrointestinal tract, which is reflected by a high absolute bioavailability of 89 % following oral administration.

Following single dose administration of meloxicam, mean maximum plasma concentrations are achieved within 5 to 6 hours.

With multiple dosing, steady state conditions were reached within 3 to 5 days.

Once daily dosing leads to drug plasma concentrations with a relatively small peak-trough fluctuation in the range of 0,4 – 1,0 µg/mL for 7,5 mg doses and 0,8 – 2,0 µg/mL for 15 mg doses, respectively (C_{min} and C_{max} at steady state, respectively). Maximum plasma concentrations of meloxicam at steady state, are achieved within five to six hours.

Continuous treatment for longer periods (e.g. six months) did not point to any changes in pharmacokinetics compared to steady state pharmacokinetics after two weeks of oral treatment with 15 mg meloxicam/day.

Extent of absorption for meloxicam following oral administration is not altered by concomitant food intake.

Distribution

Meloxicam is strongly bound to plasma proteins, essentially albumin (99 %). Meloxicam penetrates into synovial fluid to give concentrations approximately half of those in plasma.

Volume of distribution is low, on average 11 L. Interindividual variation is in the order of 30 - 40 %.

Biotransformation

Meloxicam undergoes extensive hepatic biotransformation.

Four different metabolites of meloxicam were identified in urine, which are all pharmacodynamically inactive.

Elimination

Meloxicam is excreted predominantly in the form of metabolites and

occurs to equal extents in urine and faeces. Less than 5 % of the daily dose is excreted unchanged in faeces, while only traces of the parent compound are excreted in urine.

The mean elimination half-life is 20 hours.

Total plasma clearance amounts on average to 8 mL/min.

Linearity/non-linearity:

Meloxicam demonstrates linear pharmacokinetics in the

therapeutic dose range of 7,5 mg to 15 mg following oral or intramuscular administration.

Special populations

Hepatic/renal insufficiency

Mild or moderate hepatic insufficiency and mild or moderate renal insufficiency do not have a substantial effect on meloxicam pharmacokinetics. In terminal renal failure, the increase in the volume of distribution may result in higher free meloxicam concentrations, and a daily dose of 7,5 mg must not be exceeded.

Elderly

Mean plasma clearance at steady state in elderly subjects was slightly lower than that reported for younger subjects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal silicon dioxide, crospovidone (polyplasdone XL), lactose monohydrate, magnesium stearate, microcrystalline cellulose PH 102, povidone K25 and sodium citrate dihydrate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

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

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

MELOXICAM 7,5 mg AUSTELL tablets are available in transparent PVC/PVDC -Aluminium foil blister packs of 30 tablets, packed in a dark green outer cardboard carton.

MELOXICAM 15 mg 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.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBERS

MELOXICAM 7,5 mg AUSTELL: 38/3.1/0242

MELOXICAM 15 mg AUSTELL: 38/3.1/0243

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/07/2005

10. DATE OF REVISION OF THE TEXT

22 February 2023