APPROVED PATIENT INFORMATION LEAFLET FOR MELOXICAM UNICORN 7,5 & 15

Please read this leaflet carefully before taking MELOXICAM UNICORN tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine 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.

Scheduling Status: Schedule 3

Proprietary name, Strength and Pharmaceutical Form:

MELOXICAM UNICORN 7,5 tablets (each tablet contains 7,5 mg meloxicam)

MELOXICAM UNICORN 15 tablets (each tablet contains 15 mg meloxicam)

1. WHAT MELOXICAM UNICORN CONTAINS

Active ingredient:

Meloxicam

Inactive ingredients:

Sodium Citrate, Lactose Monohydrate (Pharmatose DCL 15), Microcrystalline Cellulose (Avicel PH 102), Silica Colloidal Anhydrous (Aerosil 200), Crospovidone, Magnesium Stearate

2. WHAT MELOXICAM UNICORN IS USED FOR

MELOXICAM UNICORN is indicated for the treatment of painful inflammation of the joints (rheumatoid arthritis and osteoarthritis) and bones in the spine (ankylosing spondylitis). These tablets can also be used to relief pain in the hips.

3. BEFORE YOU TAKE MELOXICAM UNICORN

Do not take MELOXICAM UNICORN:

- If you are hypersensitive (allergic) to meloxicam or any of the other ingredients (see "**WHAT MELOXICAM UNICORN CONTAINS**").
- If you suffer from asthma, skin hives, nasal polyps or acute rhinitis (runny nose) precipitated by aspirin or other pain medication.
- If you have a stomach ulcer.
- If you suffer from severe liver impairment.
- If you suffer from non-dialysed kidney impairment.
- If you are pregnant or breast-feeding your baby.

Take special care with MELOXICAM UNICORN:

- Children under the age of 18 years should not be given these tablets.
- Patients suffering from congestive heart failure.

Patients with a history of stomach ulcers/ bleeding should discontinue taking **MELOXICAM UNICORN** if ulceration or bleeding occurs.

Your kidney function should be carefully monitored if you are dehydrated, suffer from kidney or liver dysfunction or taking diuretic agents (water tablets).

Taking MELOXICAM UNICORN with food or drink:

MELOXICAM UNICORN should be administered with food and a glass of water. Avoid the use of alcohol.

Pregnancy and breastfeeding:

The safety and efficacy in pregnancy and breastfeeding has not been proven.

Driving and using machinery:

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

Using other medicines with MELOXICAM UNICORN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **MELOXICAM UNICORN** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Simultaneous use of **MELOXICAM UNICORN** with the following medicine can have unwanted interactions. Please inform your doctor or pharmacist if you are taking or have taken any of the following:

- Aspirin and other anti-inflammatory medication: Co-administration results in an increase in stomach ulceration and/or bleeding.
- Medicines which prevent blood clotting or “blood-thinning” medicines, such as warfarin.
- Medicines which break down blood clots (thrombolytics / anti-platelet medicines)
- Lithium (psychiatric medicine used to treat mood disorders).
- Methotrexate (used in the treatment of tumours, severe skin conditions and active rheumatoid arthritis).
- Medicines used to treat high blood pressure medicines especially from the ACE inhibitors group, such as enalapril.
- Corticosteroids (used to treat various inflammatory or skin conditions).
- Cholestyramine (used to lower cholesterol levels).
- Cyclosporin (used after organ transplants or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome).
- Selective serotonin re-uptake inhibitors used in the treatment of depression.

- Diuretics or “water tablets” – your doctor may need to monitor your kidney function if you are taking any diuretics.
- The efficacy of intrauterine devices is decreased when using **MELOXICAM UNICORN** and extra methods of contraception should be used.

4. HOW TO USE MELOXICAM UNICORN

Always take **MELOXICAM UNICORN** exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of **MELOXICAM UNICORN** is too strong or too weak, talk to your doctor or pharmacist.

The dose of **MELOXICAM UNICORN** in patients with end stage renal disease on haemodialysis should not exceed 7,5 mg per day.

Adults

The maximum daily dose is 15 mg.

Your doctor will indicate the dosage that suitable for your condition. The maximum dosage should not be exceeded.

If you take more MELOXICAM UNICORN than you should:

In the event of overdosage, consult your doctor or seek help at the nearest hospital or poison control centre.

If you forget to MELOXICAM UNICORN:

Do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

5. POSSIBLE SIDE EFFECTS

MELOXICAM UNICORN can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Accelerated heart beat.
- Allergic reaction: cough; difficulty swallowing; dizziness; fast heartbeat; hives; itching, puffiness or swelling of the eyelids or around the eyes, face, lips or tongue; shortness of breath; skin rash; tightness in chest; unusual tiredness or weakness; wheezing.
- Yellow eyes or skin.
- Bronchospasm (cough; difficulty breathing; noisy breathing; shortness of breath; tightness in chest; wheezing).

These are all very serious side effects. You may need urgent medical attention. The frequency of occurrence is less frequent.

Side-effects indicating the need for medical attention only if they persist or become bothersome:

- Unusual tiredness or weakness.
- Swelling of feet, ankles, lips and tongue.
- Headache, dizziness and light-headedness.
- Indigestion, nausea and vomiting, diarrhoea, flatulence and constipation.
- Itching.

The above mentioned side-effects occur frequently.

Less frequently reported side-effects are:

- Confusion, drowsiness, sleep disturbances and nightmares.
- Stomach bleeding.
- Visual disturbances.

- Flushing, increased sensitivity of the skin to sunlight.

If you notice any side-effect not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF MELOXICAM UNICORN

- Store below 25ºC.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

7. PRESENTATION OF MELOXICAM UNICORN

MELOXICAM UNICORN 7,5 tablets are packed into Aluminium/opaque PVC blister packs of 30 tablets (strips of 10's) in an outer carton.

MELOXICAM UNICORN 15 tablets are packed into Aluminium/opaque PVC blister packs of 10 tablets (strips of 10's) in an outer carton.

8. IDENTIFICATION OF MELOXICAM UNICORN

MELOXICAM UNICORN 7,5 tablets are light yellow, round biconvex, bevel-ledged tablets with B and 18 debossed on one side and plain on the reverse.

MELOXICAM UNICORN 15 tablets are light yellow, round biconvex, bevel-ledged tablets with B and 19 debossed on either side of breakline on one side and plain on the reverse.

9. REGISTRATION NUMBERS

MELOXICAM UNICORN 7,5: 38/3.1/0495

MELOXICAM UNICORN 15: 38/3.1/0496

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Unicorn Pharmaceuticals (Pty) Ltd.

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Woodstock

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7925

11. DATE OF PUBLICATION:

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