150225128022

Mobitil

Meloxicam 15 mg tablets & suppository

1- NAME OF THE MEDICINAL PRODUCT Mobitil 15 mg film coated tablets & suppository

2- QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 15 mg of Meloxicam. Each suppository contains 15 mg of Meloxicam. For a full list of excipients, see section 6.1.

3- PHARMACEUTICAL FORM Film coated tablet & suppository

4- CLINICAL PARTICULARS

4.1- Therapeutic indications
- Short-term symptomatic treatment of exacerbations of osteoarthritis,
- Long-term symptomatic treatment of rheumatoid arthritis or ankylosing spondylitis.

4.2- Posology and method of administration

Oral use: The total daily amount should be taken as a single dose, with water or another liquid, during a meal. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4). The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially in patients with osteoarthritis.
- Rheumatoid arthritis, ankylosing spondylitis: 15 mg/day (see also section 'Special populations' below)

DO NOT EXCEED THE DOSE OF 15 mg/day.

Rectal: One suppository / day.

Special populations: *Elderly patients and patients with increased risks for adverse reaction (see section 5.2)*

The recommended dose for long term treatment of rheumatoid arthritis and ankylosing spondylitis in elderly patients is 7.5 mg per day. Patients with increased risks for adverse reactions should start treatment with 7.5 mg per day (see section 4.4).

Renal impairment (see section 5.2): In dialysis patients with severe renal failure, the dose should not exceed 7.5 mg per day. No dose reduction is required in patients with mild to moderate renal impairment (i.e. patients with a creatinine clearance of greater than 25 mL/min).

(For patients with non-dialysed severe renal failure, see section 4.3)

Hepatic impairment (see section 5.2): No dose reduction is required in patients with mild to moderate hepatic impairment.

(For patients with severely impaired liver function, see section 4.3).

Children and adolescents: Mobil 7.5 mg tablets is contraindicated in children and adolescents aged under 16 years (see section 4.3).

4.3- Contraindications This medicinal product is contraindicated in the following situations:
- 3rd trimester of pregnancy (see section 4.6 "Pregnancy and lactation");
- children and adolescents aged under 16 years;
- hypersensitivity to meloxicam or to one of the recipients or hypersensitivity to substances with a similar action, i.e., NSAIDs, aspirin. Meloxicam should not be given to patients who have developed signs of asthma, nasal polyps, angioneurotic edema or urticaria following the administration of aspirin or other NSAIDs;
- history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy;
- active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding);
- severely impaired liver function;
- severe renal failure;
- gastrointestinal bleeding, history of cerebrovascular bleeding or other bleeding disorders;
- severe heart failure.

4.4- Special warnings and precautions for use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.2, and GI and cardiovascular risks below). The recommended maximum daily dose should not be exceeded in case of insufficient therapeutic effect, nor should an additional NSAID be added to the therapy because this may increase the toxicity while therapeutic advantage has not been proven. The use of meloxicam with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. Meloxicam is not appropriate for the treatment of patients requiring relief from acute pain. In the absence of improvement after several days, the clinical benefit of the treatment should be reassessed. Any history of oesophagitis, gastritis and/or peptic ulcer must be considered in order to ensure their total cure before starting treatment with meloxicam. Attention should routinely be paid to the possible onset of a recurrence in patients treated with meloxicam and with a past history of this type.

Gastrointestinal effects GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 4.3), and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g., misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk (see below and 4.5). Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment. Caution is advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as hepatic or systemic corticosteroids, anticoagulants such as warfarin, or other non steroidal anti-inflammatory drugs, including acetylsalicylic acid anti-inflammatory dosage (≥ 1g as single intake or ≥3g as total daily amount) (see section 4.5). When GI bleeding or ulceration occurs in patients receiving meloxicam, the treatment should be withdrawn. NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated (see section 4.8 - undesirable effects).

Cardiovascular and cerebrovascular effects

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy. Clinical monitoring of blood pressure for patients at risk is recommended at baseline and especially during treatment initiation with meloxicam. The use of some NSAIDs including meloxicam (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). There are insufficient data to exclude such a risk for meloxicam. Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with meloxicam after careful consideration. Similar consideration should be made before initiating long-term treatment of patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).

Skin reactions 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 NSAIDs (see section 4.8). 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 should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Parameters of liver and renal function as with most NSAIDs, occasional increases in serum transaminase levels, increases in serum bilirubin or other liver function parameters, as well as increases in serum creatinine and blood urea nitrogen and other laboratory disturbances, have been reported. The majority of these instances are temporary and mild. Should any such abnormality prove significant or persistent, the administration of Mobicam should be stopped and appropriate investigations undertaken.

Functional failure NSAIDs, by inhibiting the vasodilating effect of renal prostaglandins, may induce a functional renal failure by reduction of glomerular filtration. This adverse event is dose-dependant. At the beginning of the treatment, or after dose increase, careful monitoring of diuresis and renal function is recommended in patients with the following risk factors:
- Elderly
- Cardiac failure
- Concomitant treatments such as ACE inhibitors, angiotensin-II antagonists, diuretics. (See section 4.5). Interaction with other medicinal products and other forms of interaction)
- Hypovolemia (whatever the cause)
- Renal failure
- Congestive heart failure
- Renal bruit
- Nephrotic syndrome
- Lupus nephropathy
- Severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score ≥ 10)

In rare instance NSAIDs may be the cause of interstitial nephritis, glomerulonephritis, renal papillary necrosis or nephrotic syndrome. The dose of meloxicam in patients with end-stage renal failure on haemodialysis should not be higher than 7.5 mg. 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).

Sodium, potassium and water retention Retention of sodium, potassium and water retention and interference with the nutritionic effects of diuretics may occur with NSAIDs. Furthermore, a decrease of the antihypertensive effect of antihypertensive drugs can occur (see section 4.5). Consequently, oedema, cardiac failure or hypertension may be precipitated or exacerbated in susceptible patients as a result. Clinical monitoring is therefore necessary for patients at risk (See sections 4.2 and 4.3).

Hyperkalaemia Hyperkalaemia can be favoured by diabetes or concomitant treatment known to increase potassium (see section 4.5). Regular monitoring of potassium values should be performed in such cases.

Other warnings and precautions Adverse reactions are often less well tolerated in elderly, fragile or weakened individuals, who therefore require careful monitoring, as with other NSAIDs, particular caution is required in the elderly, in when frail, hepatic and cardiac functions are frequently impaired. The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal (see section 4.2).

Meloxicam, as any other NSAID may mask symptoms of an underlying infectious disease. The use of meloxicam, as with any drug known to inhibit cyclooxygenase / prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive. In women who have difficulties for conceiving, or who are undergoing investigation of infertility, withdrawal of meloxicam should be considered.

- Cardiovascular Risk

NSAIDs may cause an increased 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. NSAIDs is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

- Gastrointestinal Risk NSAIDs cause an increased risk of serious gastrointestinal adverse events including inflammation, bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Effects on the ability to drive and use machines:

There are no specific studies about effects on the ability to drive vehicles and to use machinery. Patients who experience visual disturbances, drowsiness or other central nervous system disturbances should refrain from these activities.

- This product contains benzyl alcohol which is potentially toxic when administered locally to neural tissue.

Drug Interactions:

* Other NSAIDs Including salicylates: the concomitant administration of more than one NSAID may increase the risk of gastrointestinal ulceration and bleeding through synergistic action.
* Lithium: NSAIDs have been reported to increase serum lithium levels. It is recommended that plasma lithium levels be monitored when initiating, adjusting discontinuing Mobitil.
* Methotrexate: As other NSAIDs, Mobitil may increase the haematologic toxicity of methotrexate. In this situation, strict monitoring of blood cell count is recommended.
* Contraception: NSAIDs have been reported to decrease the efficacy of intrauterine devices.
* Diuretics: Treatment with NSAIDs is associated with the potential for acute renal insufficiency in patients who are dehydrated.

Patients receiving Mobitil and diuretics should be adequately hydrated and be monitored for renal function prior to initiating treatment.

* Nephrotoxicity of cyclosporin may be enhanced by NSAIDs via renal prostaglandin mediated effects. During combined treatment renal function is to be measured.
* Antihypertensives (eg.,β-Blockers, ACE-inhibitors, vasodilators, diuretics): A reduced effect of the antihypertensive drug by inhibition of vasodilating prostaglandins has been reported during treatment with NSAIDs.
* Cholestyramine binds meloxicam in the gastrointestinal tract leading to a faster elimination of meloxicam. Meloxicam 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 and drugs known to inhibit, or to be metabolized by, CYP 2C9 and/or CYP 3A4 are administered concurrently. No relevant pharmacokinetic drug-drug interactions were detected with respect to the concomitant administration of antacids, cimetidine, digoxin and furosemide. Interactions with oral antidiabetics cannot be excluded. Mobitil ampoules must not be mixed with other drugs in the same syringe since there is no information about possible incompatibilities.

Pregnancy and Lactation: Although no teratogenic effects were seen in preclinical testing, Mobitil should not be used during pregnancy and breastfeeding.

Side Effects: The following adverse events which may be causally related with the administration of Mobitil have been reported. The frequencies given below are based on corresponding occurrences in clinical trials, regardless of any causal relationship. The information is based on clinical trials involving 3750 patients who have been treated with daily oral doses of 7.5 or 15 mg meloxicam tablets over a period of up to 18 months (mean duration of treatment 127 days), and on 254 patients who have been treated with intramuscular injections of Mobitil for up to seven days. The incidence of adverse events which may be causally related to the administration of Mobitil that have come to light as a result of reports received in relation to its administration of oral formulations of the marketed product are difficult to quantify. All are assumed to occur with a frequency of less than 0.1%.

Gastrointestinal:
more frequent than 1%: dyspepsia, nausea, vomiting, abdominal pain, constipation, flatulence, diarrhea.
between 0.1% and 1%: transitory abnormalities of liver function parameters (eg, raised transaminases or bilirubin), eructation, oesophagitis, gastroduodenal ulcer, occult or macroscopic gastrointestinal bleeding.
less frequent than 0.1%: gastrointestinal perforation, colitis, hepatitis, gastritis.

Hematological:
more frequent than 1%: anemia
between 0.1% and 1%: disturbances of blood count, including differential white blood cell count, leukopenia and thrombocytopenia. Concomitant administration of a potentially myelotoxic drug in particular methotrexate, appears to be a predisposing factor to the onset of a cytopenia.

Dermatological:
more frequent than 1%: pruritus, skin rash
between 0.1% and 1%: stomatitis, urticaria
less frequent than 0.1%: photosensitization. On rare occasions bullous reactions, erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis may develop

Respiratory:
less frequent than 0.1%: onset of acute asthma has been reported in certain individuals following the administration of aspirin or other NSAIDs, including Mobitil

Central Nervous System:
more frequent than 1%: lightheadedness, headache
between 0.1% and 1%: vertigo, tinnitus, drowsiness
less Frequent than 0.1%: confusion, disorientation, alteration of mood

Cardiovascular:
more frequent than 1%: oedema
between 0.1% and 1%: increase in blood pressure, palpitations, flushes

Genitourinary:
between 0.1% and 1%: atinormal renal function parameters (increased serum creatinine and/or serum urea).
less frequent than 0.1%: acute renal failure

Vision Disorders:
less frequent than 0.1%: conjunctivitis, visual disturbances including blurred vision

Hypersensitivity Reactions:
less frequent than 0.1%: angio-oedema and immediate hypersensitivity reactions, including anaphylactoid/anaphylactic reactions

Application Side Disorders:
more frequent than 1%: injection site mass
between 0.1 and 1%: injection site pain

Dosage and Administration: Intramuscular administration should only be used during the first few days of treatment. For continuation of treatment, oral (tablets) formulations should be used.

The recommended dosage of Mobitil is 7.5 mg or 15mg once daily, depending on the pain intensity and severity of inflammation.

Mobitil should be administered by deep intramuscular injection. Because of the possibility of incompatibilities, Mobitil ampoule should not be mixed with other drugs in the same syringe.

The maximum daily dose of Mobitil in patients with severe renal failure on haemodialysis should not be higher than 7.5 mg.

Mobitil ampoules should not be administered intravenously.

As a dosage in children and adolescents has not yet been established usage of the ampoules should be restricted to adults.

Combined Administration: The total daily dose of Mobitil administered as tablets, suppositories and injections should not exceed 15 mg.

Overdosage: In case of overdose the standard measures of gastric evacuation and general supportive measures should be used as there is no known antidote.

It has been shown in a clinical trial that cholestyramine accelerates the elimination of meloxicam.

Availability: Carton box containing three 1.5 ml ampoules.

Storage instructions: Store at room temperature

This is a medicament

* Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
* Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament
* The doctors and the pharmacist are experts in medicine, its benefits and risks.
* Do not by yourself interrupt the period of treatment prescribed for you.
* Do not repeat the same prescription without consulting your doctor.

Manufactured by:
Medical Union Pharmaceuticals,
Abu-Sultan, Ismailia, Egypt
Issue Date: 20/9/2004, Revision date: 14 / 1 / 2013

150225116015

Mobitil

ampoules

Composition: 1 ampoule of 1.5 ml contains 15 mg meloxicam

Excipients: Nicotinamide, benzyl alcohol, propylene glycol, sodium hydroxide pellets, monobasic potassium phosphate (anhydrous).

This product contain benzyl alcohol, which may be fatal in neonates and infants.

Properties: Mobitil is a non-steroidal anti-inflammatory drug (NSAID) of the enolic acid class, which has shown anti-inflammatory, analgesic and antipyretic properties in animals. Meloxicam showed potent anti-inflammatory activity in all standard models of inflammation. A common mechanism for the above effects may exist in the ability of meloxicam to inhibit the biosynthesis of prostaglandins, known mediators for inflammation. Comparison of the ulcerogenic dose and the anti-inflammatory effective dose in the rat adjuvant arthritis model confirmed a superior therapeutic margin in animals over standard NSAIDs. In vivo, meloxicam inhibited prostaglandin biosynthesis more potently at the site of inflammation than in the gastric mucosa or the kidney. The differences are thought to be related to a selective inhibition of COX-2 activity and it is believed that COX-2 inhibition provides the therapeutic effects of NSAIDs whereas inhibition of constitutive COX-1 may be responsible for gastric and renal side effects. The COX-2 selectivity of meloxicam has been confirmed both in vitro and ex vivo in a number of test systems. In the human whole body assay meloxicam has been shown in vitro to inhibit COX-2 selectively. Meloxicam (7.5 and 15 mg) demonstrated a greater inhibition of COX-2 ex vivo, as demonstrated by a greater inhibition of lipopolysaccharide-stimulated PGE2 production (COX-2) as compared with thromboxane production in clotting blood (COX-1). These effects were dose-dependent. Meloxicam has been demonstrated to have no effect on either platelet aggregation or bleeding time at recommended time ex vivo, while indomethacin, diclofenac, ibuprofen and naproxen significantly inhibited platelet aggregation and prolonged bleeding. In clinical trials, gastro-intestinal adverse events overall were reported less frequently with meloxicam 7.5 mg and 15 mg than with the NSAIDs with which it has been compared, due predominantly to a lower reporting incidence of events such as dyspepsia, vomiting, nausea and abdominal pain. The incidence of upper gastro-intestinal perforation, ulcers, and bleeds reported in association with meloxicam is low and dose dependent. There is no single study powered adequately to detect statistically differences in the incidence of clinically significant upper gastro-intestinal perforation, obstruction, or bleeds between meloxicam and other NSAIDs. A pooled analysis has been conducted involving patients treated with meloxicam daily in 35 clinical trials in the indications osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. Exposure to meloxicam in these trials ranged from 3 weeks to one year (most patients were enrolled in one-month studies). Almost all patients participated in trials that permitted enrolment of patients with a prior history of gastro-intestinal perforation, ulcer or bleeding. The incidence of clinically significant upper gastro-intestinal perforation, obstruction or bleeding (POB) was assessed retrospectively following independent blinded review of cases.

Indications: Short term symptomatic treatment of acute exacerbations of inflammatory rheumatisms.

Contraindications: Known hypersensitivity to meloxicam or any excipient of the product. There is a potential for cross sensitivity to aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs). Mobitil should not be given to patients who have developed signs of asthma, nasal polyps, angio-oedema or urticaria following the administration of aspirin or other NSAIDs. Mobitil ampoules should not be used in patients treated with anticoagulants as intramuscular haematomas may occur.

- Active peptic ulcer.
- Severe hepatic insufficiency.
- Non-dialysed severe renal insufficiency.
- Children and adolescents aged less than 15 years.
- Pregnancy or breastfeeding.

pregnancy, Nursing Mothers & Pediatric use

- Do not administer Injections preserved with benzyl alcohol to premature infants, neonates, infants below 13 years, pregnant women or nursing mothers. Benzyl alcohol has been associated with serious adverse events & death, particularly in pediatric patients (it may cause Gasping Syndrome) Injections preservative free should be used in these populations.

SpecialPrecautions:

As with other NSAIDs, caution should be exercised when treating patients with a history of upper gastrointestinal disease. Patients with gastrointestinal symptoms should be monitored. Mobitil should be withdrawn if peptic ulceration or gastrointestinal bleeding occurs. Gastrointestinal bleeding, ulceration or perforation, potentially fatal, can occur at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events. The consequences of such events are generally more serious in the elderly. Special attention should be paid in patients reporting mucocutaneous adverse events and consideration given to discontinuing Mobitil. NSAIDs inhibit 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, administration of an NSAID may precipitate overt renal decompensation which is typically followed by recovery to pretreatment state upon discontinuation of non-steroidal anti-inflammatory therapy. Patients at greatest risk of such a reaction are dehydrated patients, those with congestive heart failure, liver cirrhosis, nephrotic syndrome and overt renal disease, those receiving a diuretic, or those having undergone major surgical procedures which lest to hypovolaemia. In such patients, volume of diuresis and renal function should be carefully monitored at the beginning of therapy. In rare instances, NSAIDs may be the cause of interstitial nephritis, glomerulonephritis, renal medullary necrosis or nephrotic syndrome. As with other NSAIDs, occasional elevations of serum transaminases or other parameters 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, Mobitil should be stopped and follow-up tests carried out. No dose reduction is required in patients with clinically stable liver cirrhosis. Frail or debilitated patients may tolerate side effects less well and such patients should be carefully supervised. As with other NSAIDs, caution should be used in the treatment of elderly patients who are more likely to be suffering from impaired renal, hepatic or cardiac function. Induction of sodium, potassium and water retention and interference with the nutritionic effects of diuretics may occur with NSAIDs. Cardiac failure or hypertension may be precipitated or exacerbated in susceptible patients as a result.

Warnings:

- Cardiovascular Risk NSAIDs may cause an increased 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 o NSAIDs is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
- Gastrointestinal Risk NSAIDs cause an increased risk of serious gastrointestinal adverse events including inflammation, bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Effects on the ability to drive and use machinus:

There are no specific studies about effects on the ability to drive vehicles and to use machinery. Patients who experience visual disturbances, drowsiness or other central nervous system disturbances should refrain from these activities.

- This product contains benzyl alcohol which is potentially toxic when administered locally to neural tissue.

Drug Interactions:

* Other NSAIDs Including salicylates: the concomitant administration of more than one NSAID may increase the risk of gastrointestinal ulceration and bleeding through synergistic action.
* Lithium: NSAIDs have been reported to increase serum lithium levels. It is recommended that plasma lithium levels be monitored when initiating, adjusting discontinuing Mobitil.
* Methotrexate: As other NSAIDs, Mobitil may increase the haematologic toxicity of methotrexate. In this situation, strict monitoring of blood cell count is recommended.
* Contraception: NSAIDs have been reported to decrease the efficacy of intrauterine devices.
* Diuretics: Treatment with NSAIDs is associated with the potential for acute renal insufficiency in patients who are dehydrated.

Patients receiving Mobitil and diuretics should be adequately hydrated and be monitored for renal function prior to initiating treatment.

* Nephrotoxicity of cyclosporin may be enhanced by NSAIDs via renal prostaglandin mediated effects. During combined treatment renal function is to be measured.
* Antihypertensives (eg.,β-Blockers, ACE-inhibitors, vasodilators, diuretics): A reduced effect of the antihypertensive drug by inhibition of vasodilating prostaglandins has been reported during treatment with NSAIDs.
* Cholestyramine binds meloxicam in the gastrointestinal tract leading to a faster elimination of meloxicam. Meloxicam 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 and drugs known to inhibit, or to be metabolized by, CYP 2C9 and/or CYP 3A4 are administered concurrently. No relevant pharmacokinetic drug-drug interactions were detected with respect to the concomitant administration of antacids, cimetidine, digoxin and furosemide. Interactions with oral antidiabetics cannot be excluded. Mobitil ampoules must not be mixed with other drugs in the same syringe since there is no information about possible incompatibilities.

Pregnancy and Lactation: Although no teratogenic effects were seen in preclinical testing, Mobitil should not be used during pregnancy and breastfeeding.

Side Effects: The following adverse events which may be causally related with the administration of Mobitil have been reported. The frequencies given below are based on corresponding occurrences in clinical trials, regardless of any causal relationship. The information is based on clinical trials involving 3750 patients who have been treated with daily oral doses of 7.5 or 15 mg meloxicam tablets over a period of up to 18 months (mean duration of treatment 127 days), and on 254 patients who have been treated with intramuscular injections of Mobitil for up to seven days. The incidence of adverse events which may be causally related to the administration of Mobitil that have come to light as a result of reports received in relation to its administration of oral formulations of the marketed product are difficult to quantify. All are assumed to occur with a frequency of less than 0.1%.

Gastrointestinal:
more Frequent than 1%: dyspepsia, nausea, vomiting, abdominal pain, constipation, flatulence, diarrhea.
between 0.1% and 1%: transitory abnormalities of liver function parameters (eg, raised transaminases or bilirubin), eructation, oesophagitis, gastroduodenal ulcer, occult or macroscopic gastrointestinal bleeding.
less frequent than 0.1%: gastrointestinal perforation, colitis, hepatitis, gastritis.

Hematological:
more frequent than 1%: anemia
between 0.1% and 1%: disturbances of blood count, including differential white blood cell count, leukopenia and thrombocytopenia. Concomitant administration of a potentially myelotoxic drug in particular methotrexate, appears to be a predisposing factor to the onset of a cytopenia.

Dermatological:
more frequent than 1%: pruritus, skin rash
between 0.1% and 1%: stomatitis, urticaria
less frequent than 0.1%: photosensitization. On rare occasions bullous reactions, erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis may develop

Respiratory:
less frequent than 0.1%: onset of acute asthma has been reported in certain individuals following the administration of aspirin or other NSAIDs, including Mobitil

Central Nervous System:
more frequent than 1%: lightheadedness, headache
between 0.1% and 1%: vertigo, tinnitus, drowsiness
less Frequent than 0.1%: confusion, disorientation, alteration of mood

Cardiovascular:
more frequent than 1%: oedema
between 0.1% and 1%: increase in blood pressure, palpitations, flushes

Genitourinary:
between 0.1% and 1%: atinormal renal function parameters (increased serum creatinine and/or serum urea).
less frequent than 0.1%: acute renal failure

Vision Disorders:
less frequent than 0.1%: conjunctivitis, visual disturbances including blurred vision

Hypersensitivity Reactions:
less frequent than 0.1%: angio-oedema and immediate hypersensitivity reactions, including anaphylactoid/anaphylactic reactions

Application Side Disorders:
more frequent than 1%: injection site mass
between 0.1 and 1%: injection site pain

Dosage and Administration: Intramuscular administration should only be used during the first few days of treatment. For continuation of treatment, oral (tablets) formulations should be used.

The recommended dosage of Mobitil is 7.5 mg or 15mg once daily, depending on the pain intensity and severity of inflammation.

Mobitil should be administered by deep intramuscular injection. Because of the possibility of incompatibilities, Mobitil ampoule should not be mixed with other drugs in the same syringe.

The maximum daily dose of Mobitil in patients with severe renal failure on haemodialysis should not be higher than 7.5 mg.

Mobitil ampoules should not be administered intravenously.

As a dosage in children and adolescents has not yet been established usage of the ampoules should be restricted to adults.

Combined Administration: The total daily dose of Mobitil administered as tablets, suppositories and injections should not exceed 15 mg.

Overdosage: In case of overdose the standard measures of gastric evacuation and general supportive measures should be used as there is no known antidote.

It has been shown in a clinical trial that cholestyramine accelerates the elimination of meloxicam.

Availability: Carton box containing three 1.5 ml ampoules.

Storage instructions: Store at room temperature

This is a medicament

* Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
* Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament
* The doctors and the pharmacist are experts in medicine, its benefits and risks.
* Do not by yourself interrupt the period of treatment prescribed for you.
* Do not repeat the same prescription without consulting your doctor.

Manufactured by:
Medical Union Pharmaceuticals,
Abu-Sultan, Ismailia, Egypt
Issue Date: 20/9/2004, Revision date: 14 / 1 / 2013

150225128022

موبيتيل

سيلوكسيكام ١٥ مجم أقراص و أقماع

رجاءاً اقرأ هذه النشرة بعناية. تحتوى هذه النشرة على ملخص المعلومات المتاحة عن الدواء.
هذه المعلومات تتطبق على مستحضر موبيتيل ١٥ مجم أقراص وموبيتيل ١٥ مجم أقماع.
لو كان لديك أى أسئلة بعد قراءة هذه النشرة، اسأل طبيبك أو الصيدلى.
ماذا يوجد داخل المستحضر؟ يوجد داخل المستحضر هو موبيتيل ١٥ مجم أقراص وموبيتيل ١٥ مجم أقماع.

ما محتويات هذا المستحضر؟

الأقراص: يحتوى القرص الواحد على **١٥ مجم سيلوكسيكام كمادة فعالة.** كما يحتوى القرص أيضاً على المواد غير الفعالة الآتية: بيتا- سيكلوديكسترين، بولى سوربيت ٨٠، ميكرو كريستالين سيليولوز، اميسلز شبه قاعدى (١٠٠)، ديترى كسى ميثال سيليولوز، سيليكون دايوكسيد غيرى (أيروسيل – ٢٠٠)، كروسكارميلوز، ستيارات الماغنسيوم، برلى ايفلين جليكول ٦٠٠٠، تيتانيوم دايوكسيد، تلك، أوكسيد الحديد.

الأقماع: يحتوى القمع الواحد على **١٥ مجم سيلوكسيكام كمادة فعالة.** كما يحتوى القمع أيضاً على المواد غير فعالة: بيتاسيكلو ديكسترين، برلى سوربيت ٨٠، دو بويل جلاكات، دهون صلبة، دو بيسيلين جليكول، تسميح سنتطب سيلوكسيكام وحيل.

موبيتيل ١٥ مجم أقراص متوافر فى علبة كرتون تحتوى على ١٠ أقراص.
موبيتيل ١٥ مجم أقماع متوافر فى علبة كرتون تحتوى على ٦ أقماع.

ما هو مستحضر موبيتيل ١٥ مجم أقراص أو أقماع؟

يحتوى أقراص أو أقماع موبيتيل ١٥ مجم على سيلوكسيكام كمادة فعالة. ينتمى سيلوكسيكام إلى مجموعة مركبات يطلق عليها مضادات الالتهاب غير الستيروئيدية والتى تستعمل لتخفيف أعراض الالتهاب والآلام المفاصل و العضلات.

قمستعمالك مستحضر موبيتيل ١٥ مجم أقراص أو أقماع

• لايستعمل هذا المستحضر فى الحالات الآتية:
– إذا كنت حاملاً أو تخططين لحدوث حمل، أو إذا كنت تقومين بالرضاعة.
– إذا كانت لديك حساسية لأى مستحضر آخر غير الستيروئيدية الأخرى.
– إذا عانيت من أزمة سابقة، أو إذا كنت تعانين من حساسية الالتهاب غير الستيروئيدية الأخرى.
– إذا كنت لديك أى قرحة بالجهاز الهضمى أو نزيف فى الجهاز الهضمى لأنك سبق وعانيت من قرحة أو نزيف.
– إذا كنت لديك أى قرحة من قبل قرحة بالجهاز الهضمى (أى المعدة أو الأمعاء).
– إذا كنت لديك أى اضطراب فى الكبد أو الكلى.
– إذا كنت لديك أى اضطراب فى القلب أو عانيت من أزمة فى القلب.
– إذا كنت لديك أى نزيف بالأوعية الدموية الدماغية (نزيف بالمخ).
– إذا كنت لديك أى أزمة شديدة بالقلب.
– إذا كنت لديك مرض شديد بالكلية أو إذا كنت تقوم بعمل كلوى.
– إذا كنت تعانين من اضطراب شديد بعملية التبول.
• يجب اتخاذك الحيطة عند استعمالك الدواء فى الحالات الآتية:
• إذا كنت تعانين من التهاب بالمرئ أو التهاب بالمثانة أو إذا مرض أخر بالجهاز الهضمى مثل التهاب القولون التقرحى، أو مرض كرون.
• إذا كنت تعانين من ارتفاع ضغط الدم.
• إذا كنت تعانين من مرض السكر.
• إذا كنت تعانين من مرض السكر.
• إذا كان قد تم تشخيص حالتك، من قبل على أن لديك ارتفاع فى مستويات البوتاسيوم بالدم.
• رسوب يراقب الطبيب تطور حالتك، إنك ماتزة علاجك.

تحذيرات لو استعمال أدوية مثل سيلوكسيكام ١٥ مجم أقراص أو أقماع قد تصابحين زيادة فطورة فى مخاطر الإصابة بنزيات قلبية (احتشاء عضلة القلب) أو نزيف دماغى، تزداد الخطورة مع استعمال الدواء بجرعات عالية أو لفترة طويلة. لاتقم بتخطى الجرعات المرصوفة أو الفترة العلاجية المحددة. إذا كانت لديك مشاكل بالقلب، أو كنت قد أصبت بنزيف دماغى من قبل، أو إذا كنت تعانين قد تعرض لتلك المخاطر (مثلاً إذا كان لديك ارتفاع فى ضغط الدم، أو كنت مريضاً بالسكر، أو إذا كان لديك ارتفاع فى نسبة الكولسترول، أو إذا كنت مدخناً) يجب عليك مناقشة العلاج مع طبيبك أو الصيدلى.

الحمل لايجب استعمال هذا المستحضر إذا كنت حاملاً، أو تخططين لحدوث حمل أو لا تخططين لحدوث حمل، أو إذا ظهرت بحدوث حمل، تحدثى مع طبيبك لاعطائك النصيحة.

الرضاعة لايجب استعمال الأدوية المرصعات إذا المستحضر.

إفادة مركبة و تشغيل ماكينات: قد تحدث اضطرابات بالرؤية، دوخة أو دوار أثناى مع هذا الدواء. إذا كنت لك أى من هذه، التنزيد، لاتقم بقيادة سيارة، أو تشغيل ماكينات.

المخاطر على القلب والأوعية الدموية

• المسكنات الغير ستيروئيدية قد تسبب زيادة احتمالات حدوث الجلطات القلبية أو عائية، احتشاء عضلة القلب، أو السكتة الدماغية، والتى يمكن أن تكون قاتلة. وهذه المخاطر قد تزيد مع زيادة فترة الاستخدام، إن المرضى الذين يعانون من أمراض القلب أو الأوعية الدموية أو لديهم احتمالية عالية للإصابة بتلك الأمراض يكون لديهم احتمال أكبر لخطر الإصابة بتلك الأمراض.

• إن المنزلكسيكام محظور استخدامه لعلاج آلام الناتج إن حالات العمليات الجراحية لتحويل مسار الشريان التاجى.

المخاطر على الجهاز الهضمى

•• المسكنات الغير ستيروئيدية تسبب زيادة احتمالات بحدوث بعض الآثار الجانبية الخطيرة بما فى ذلك النزيف والتقرح فى الجهاز الهضمى، وتثقب جدار المعدة أو الأمعاء، والتى يمكن أن تكون قاتلة. ويمكن لهذه الآثار أن تحدث فى أى وقت خلال الاستخدام ودون أعراض كسابق إنذار. المرضى كبار السن هم أكثر عرضة للاحداث المعدية المعوية الخطيرة.

استعمال أدوية أخرى: بما أن مستحضر موبيتيل ١٥ مجم أقراص أو أقماع أنه يؤثر على/ أو يتأثر باستعمال أدوية أخرى، فرجاءاً اخبر الطبيب أو الصيدلى إذا كنت قد استعملت مؤخراً أى دواء آخر، حتى ولو كان بدون وصفة طبية.

رجاءاً أخبر الطبيب أو الصيدلى بشكل خاص إذا كنت تستعمل أو قد استعملت أى دواء الآتية:
• مضادات الالتهاب غير الستيروئيدية الأخرى بما فيها الأسبيرين.
• الكورتيكوستيرويدات.
• مضادات الالتهاب قلم مال الأرفارين.
• مثبيات الصفائح.
• أدوية علاج ارتفاع ضغط الدم.
• السايكلوسبورين (دواء يستعمل عادة بعد زراعة الأعضاء أو لبعض الأمراض الجلدية الشديدة)، أو التهاب المفاصل الروماتويدى، أو الملازمة الكلية).
• ال