PACKAGE LEAFLET

Package leaflet: Information for the user
Mobiglan 7.5 mg Tablets
Mobiglan 15 mg Tablets
Meloxicam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Mobiglan Tablets are and what they are used for

Mobiglan Tablets contain the active substance meloxicam. Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which are used to reduce inflammation and pain in the joints and muscles.

Mobiglan Tablets are used for the:
- short-term (acute) treatment of flare ups of osteoarthritis.
- long-term treatment of
  - rheumatoid arthritis
  - ankylosing spondylitis (also known as Bechterew's disease).

2. What you need to know before you take Mobiglan Tablets

Do not take Mobiglan Tablets if:
- you are in the last three months of your pregnancy
- you are a child or adolescent under 16 years of age
- you are allergic to meloxicam or to any of the other ingredients of this medicine (listed in section 6).
- you are allergic to aspirin or other NSAIDs
- you develop any of the following signs after taking aspirin or other NSAIDs
  - wheezing, chest tightness, breathlessness (asthma)
  - nasal blockage due to swellings in the lining of your nose (nasal polyps)
  - skin rashes/nettle rash (urticaria)
  - sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioneurotic oedema)
- following previous therapy with NSAIDs you had a history of
  - bleeding in your stomach or intestines
  - holes (perforations) in your stomach or intestines
- you have ulcers or a bleeding in your stomach or intestines;
- recently you have or have history of stomach or peptic ulcers or bleeding (ulceration or bleeding occurring at least twice)

- you have severely impaired liver function
- you have non dialysed severe kidney failure
- you have recently had bleeding in the brain (cerebrovascular bleeding)
- you have any kind of bleeding disorder
- you have severe heart failure
- you have intolerance to some sugars as this product contains lactose (see also "Mobiglan Tablets contain lactose")

Tell your doctor if you are not sure about any of the conditions stated above.

Warnings and precautions
Talk to your doctor or pharmacist before taking Mobiglan Tablets.

Warnings
Medicines such as meloxicam may be associated with a small increased risk of heart attack (myocardial infarction) or stroke (apoplexy). Any risk is more likely with high doses and prolonged treatment. Do not take more than the recommended dose. Do not take Mobiglan tablets for longer than is prescribed for you (see section 3 "How to take Mobiglan tablets").

If you have heart problems, previous stroke or think that you might be at risk of these conditions, you should discuss your treatment with your doctor or pharmacist. For example, if you;
- have high blood pressure (hypertension)
- have high levels of sugar in the blood (diabetes mellitus)
- have high levels of cholesterol in the blood (hypercholesterolemia)
- are a smoker.

Stop your treatment with Mobiglan tablets immediately as soon as you notice bleeding (causing tar-coloured stools) or ulceration of your digestive tract (causing abdominal pain).

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of meloxicam, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of meloxicam, you must not be re-started on meloxicam at any time.

If you develop a rash or these skin symptoms, stop taking meloxicam, seek urgent advice from a doctor and tell them that you are taking this medicine.

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

Meloxicam may hide the symptoms of infection (e.g. fever). If you think you may have an infection you should see your doctor.

Precautions for use
As it will be necessary to adjust the treatment, it is important to ask your doctor's advice before you take meloxicam in case of:
- history of inflammation of the gullet (oesophagitis), inflammation of the stomach (gastritis) or a history of any other disease of the digestive tract e.g. Crohn's disease or Ulcerative Colitis
- high blood pressure (hypertension)
- older age
- heart, liver or kidney disease
- high levels of sugar in the blood (diabetes mellitus)

- reduced blood volume (hypovolaemia) which may occur if you have serious blood loss or burns, surgery or low fluid intake
- intolerance to some sugars diagnosed by your doctor as this product contains lactose
- high potassium levels in the blood previously diagnosed by your doctor

Your doctor will monitor your progress while you are taking meloxicam.

Other medicines and Mobiglan
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, please tell your doctor or pharmacist if you are taking/have taken or are using any of the following:
- other NSAIDs
- medicines which prevent blood clotting (e.g. warfarin, heparin)
- medicines which break down blood clots (thrombolytics)
- medicines to treat heart and kidney diseases
- corticosteroids (e.g. used against inflammation or allergic reactions)
- cyclosporin – used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome
- tacrolimus – used after organ transplant or for severe skin conditions
- any diuretic medicine ("water tablets")
  Your doctor may monitor your kidney function if you are taking diuretics
- medicine to treat high blood pressure (e.g. Beta-blockers)
- lithium - used to treat mood disorders
- selective serotonin re-uptake inhibitors (SSRIs) – used in the treatment of depression
- methotrexate – used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis
- cholestyramine - used to lower cholesterol levels

If you are in doubt about any of these medicines, ask your doctor or pharmacist.

Pregnancy, breast-feeding and fertility

Fertility
Meloxicam may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

Pregnancy
If a pregnancy is established during use of Mobiglan Tablets, then the doctor is to be notified.

During the first 6 months of pregnancy your doctor may punctually prescribe you this medical product if necessary.

During the last three months of pregnancy, do not use this product because meloxicam can have serious effects on your child, in particular cardiopulmonary and renal effects, even with only one administration.

Breast-feeding
This product is not recommended during breast feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machinery
Visual disturbances, including blurred vision, dizziness, drowsiness, vertigo or other central nervous system disturbances may occur with this product. If affected do not drive or operate machinery.

Mobiglan Tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to Take Mobiglan Tablets

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

The recommended dose is:

Flare-ups of osteoarthritis:
The usual dose is 7.5 mg a day. This may be increased to 15 mg a day.

Rheumatoid arthritis and ankylosing spondylitis:
The usual dose is 15 mg a day. Your doctor may reduce your dose to 7.5 mg a day.

Mobiglan Tablets are for oral use. They should be taken with a drink of water or other liquid and with food.
The 15 mg tablets can be divided into two equal halves, allowing a 7.5 mg dose to be achieved by taking half a tablet.

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

If any of the statements under the heading "Warnings and precautions" apply to you, your doctor may restrict your dose to 7.5 mg once a day.

Use in children and adolescents:
Mobiglan Tablets should not be given to children and adolescents under 16 years of age.

If you feel that the effect of Mobiglan Tablets is too strong or too weak, or if after several days you do not feel any improvement in your condition, talk to your doctor or pharmacist.

If you take more Mobiglan Tablets than you should:
Whether you have taken too many tablets or suspect an overdose, contact your doctor or go to your nearest hospital immediately.

Symptoms following acute NSAID 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)

These symptoms generally get better when you stop taking meloxicam. You may suffer from bleeding of the stomach or intestines (gastrointestinal bleeding).

Severe poisoning may result in serious drug reaction (see section 4):
- high blood pressure (hypertension)
- acute kidney (renal) failure
- liver (hepatic) dysfunction
- reduction/flattening or standstill of breathing (respiratory depression)
- loss of consciousness (coma)
- seizures (convulsions)

- collapse of the blood circulation (cardiovascular collapse)
- standstill of the heart (cardiac arrest)
- immediate allergic (hypersensitivity) reactions including:
    - fainting
    - shortness of breath
    - skin reactions

If you forget to take Mobiglan Tablets:
Do not take a double dose to make up for a forgotten dose. Just take the next dose at the usual time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Mobiglan Tablets and consult a doctor or your nearest hospital immediately if you notice:

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 live threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), lesions of soft tissues (mucosal lesions) or erythema multiforme (see section 2). 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 the 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
- Inflammation of the liver (hepatitis). This can cause symptoms such as:
    - yellowing of the skin or the eyeballs (jaundice)
    - pain in the abdomen
    - loss of appetite

Any side effect of the digestive tract, especially:
- bleeding (causing tar-coloured stools)
- ulceration of your digestive tract (causing abdominal pain)

Bleeding of the digestive tract (gastrointestinal bleeding), formation of ulcers or formation of a hole in the digestive tract (perforation) may sometimes be severe and potentially fatal, especially in older people.

If you have previously suffered from any symptoms of the digestive tract due to long term use of NSAIDs, seek medical advice immediately, especially if you are an older person. Your doctor may monitor your progress whilst on treatment.

If affected by visual disturbances do not drive or operate machinery.

General side effects of non-steroidal anti-inflammatory medicines (NSAIDs)
The use of some non-steroidal anti-inflammatory drugs (NSAIDs) may be associated with a small increased risk of occlusion of arterial vessels (arterial thrombosis events), e.g. heart attack (myocardial infarction) or stroke (apoplexy), particularly at high doses and in long term treatment.

Fluid retention (oedema), high blood pressure (hypertension) and heart failure (cardiac failure) have been reported in association with NSAID treatment.

The most commonly observed side effects affect the digestive tract (gastrointestinal events):
- ulcers of the stomach and upper part of the small bowels (peptic/gastroduodenal ulcers)
- a hole in the wall of the bowels (perforation) or bleeding of the digestive tract (sometimes fatal, particularly in older people)

The following side effects have been reported after NSAID administration:
- feeling sick (nausea) and being sick (vomiting)
- loose stools (diarrhoea)
- flatulence
- constipation
- abdominal pain
- tar-coloured stool due to bleeding in the digestive tract (melaena)
- vomiting of blood (haematemesis)
- inflammation with building of ulcers in the mouth (ulcerative stomatitis)
- worsening of inflammation of the digestive tract (e.g. exacerbation of colitis or Crohn's disease)

Less frequently, inflammation of the stomach (gastritis) has been observed.

Side effects of meloxicam – the active substance of Mobiglan tablets

Very common: may affect more than 1 in 10 people
- gastrointestinal adverse events such as indigestion (dyspepsia), feeling sick (nausea) and being sick (vomiting), abdominal pain, constipation, flatulence, loose stools (diarrhoea)

Common: may affect up to 1 to 10 people
- headaches

Uncommon: may affect up to 1 to 100 people
- dizziness (light-headedness)
- a feeling of dizziness or spinning (vertigo)
- somnolence (drowsiness)
- anaemia (reduction of the concentration of red blood pigment: haemoglobin)
- increase in blood pressure (hypertension)
- flushing (temporary redness of the face and neck)
- sodium and water retention
- increased potassium levels (hyperkalaemia). This can lead to symptoms such as:
  - changes to your heartbeat (arrhythmias)
  - palpitations (when you feel your heartbeat more than usual)
  - muscle weakness
- eructation
- inflammation of the stomach (gastritis)
- bleeding of the digestive tract
- inflammation of the mouth (stomatitis)
- immediate allergic (hypersensitivity) reactions
- itching (pruritus)
- skin rash
- sudden skin or mucosal swelling , such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioneurotic oedema)
- swelling caused by fluid retention (oedema), including swollen ankles/legs (oedema of the lower limbs)
- momentary disturbance of the liver function tests (e.g. raised liver enzyme like transaminases or an increase of the bile pigment bilirubin). Your doctor can detect these using a blood test.
- disturbance of laboratory tests investigating kidney (renal) function (e.g. raised creatinine or urea).

Rare: may affect up to 1 in 1,000 people

- mood disorders
- nightmares
- abnormal blood count, including
  - abnormal differential blood count
  - decreased number of white blood cells (leucocytopenia)
  - decreased number of blood platelets (thrombocytopenia)

  These side effects may lead to increased risk of infection and symptoms such as bruising and nosebleeds.
- ringing in the ear (tinnitus)
- feeling your heartbeat (palpitations)
- ulcers of the stomach or upper part of the small bowels (peptic/gastroduodenal ulcers)
- inflammation of the gullet (oesophagitis)
- onset of asthma attacks (seen in people who are allergic to aspirin or other NSAIDs)
- severe blistering of the skin or peeling (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- nettle rash (urticaria)
- visual disturbances
  - blurred vision
  - conjunctivitis (inflammation of the eyeball or eyelids)
- inflammation of the large bowel (colitis)

Very rare: may affect up to 1 in 10,000 people
- blistering reactions of the skin (bullous reactions) and erythema multiforme. Erythema multiforme is a serious reaction causing spots, red welts or purple or blistered areas. It can also affect the mouth, eyes and other moist body surfaces.
- inflammation of the liver (hepatitis). This can cause symptoms such as:
  - yellowing of the skin or the eyeballs (jaundice)
  - pain of the abdomen
  - loss of appetite
- acute failure of the kidneys (renal failure) in particular in patients with risk factors such as heart disease, diabetes or kidney disease
- a hole in the wall of the bowels (perforation)

Not known: frequency cannot be estimated from the available data
- confusion
- disorientation
- shortness of breath and skin reactions (anaphylactic/anaphylactoid reactions) caused by exposure to sunlight (photosensitivity reactions)
- heart failure (cardiac failure) has been reported in association with NSAID treatment
- complete loss of specific types of white blood cells (agranulocytosis), especially in patients who take meloxicam together with other drugs that are potentially inhibitory, depressant or destructive to a component of the bone marrow (myelotoxic drugs). This can cause:
  - sudden fever
  - sore throat
  - infections
- pancreatitis (inflammation of the pancreas)

Side effects caused by non-steroidal anti-inflammatory medicines (NSAIDs), but not yet seen after taking meloxicam

Changes to the kidney structure resulting in acute kidney failure:
- very rare cases of kidney inflammation (interstitial nephritis)
- death of some of the cells within the kidney (acute tubular or papillary necrosis)
- protein in the urine (nephrotic syndrome with proteinuria)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mobiglan Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Mobiglan Tablets do not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Mobiglan Tablets contain
- The active substance is Meloxicam. Each tablet contains 7.5 mg or 15 mg of Meloxicam.
- The other ingredients are sodium citrate, lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal anhydrous silica and magnesium stearate.

What Mobiglan Tablets look like and contents of the pack
Mobiglan 7.5mg Tablets are light yellow, round, biconvex bevelled edge tablets with B and 18 on one side and plain on the other side.
Mobiglan 15mg Tablets are light yellow, round, biconvex bevelled edge tablets with B and 19 on either side of a scoreline on one side and plain on the other side.
Mobiglan 7.5mg and 15mg Tablets are available in blister packs containing 30 tablets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder
Niche Generics Limited,
1 The Cam Centre,
Wilbury Way,
Hitchin Hertfordshire SG4 0TW,
United Kingdom

Manufacturer:
Niche Generics Ltd.
Unit 5, 151 Baldoyle Industrial Estate, Baldoyle
Dublin 13
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Spain	Meloxicam UR 7,5 & 15 Comprimidos EFG
Ireland	Mobiglan 7.5mg & 15mg Tablets
Czech Republic	Melocox 15mg Tablets

This leaflet was last revised in July 2017.