PACKAGE LEAFLET: INFORMATION FOR THE USER

Relifex® 500mg Film-coated Tablets
(nabumetone)

The name of your medicine is Relifex 500mg film coated tablets, but will be referred to as Relifex tablets throughout this leaflet.

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 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 Relifex tablets are and what they are used for

Relifex tablets contain the active ingredient nabumetone, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
Relifex tablets are used for the management of arthritis such as:

- Osteoarthritis
- Rheumatoid arthritis
- Spondylitis (inflammation of the spine)
- Gout (inflammation of a joint - often the big toe) and
- Muscle injuries

2. What you need to know before you take Relifex tablets

Do not take Relifex tablets:

- If you are allergic to Nabumetone.
- If you have experienced asthma, hives or an allergic reaction to other similar drugs (NSAIDs).
- If you are allergic to any of the other ingredients of Relifex tablets (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- If you have or have had a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach (2 or more episodes).
- If you have had bleeding or ulceration of the upper gastrointestinal tract related to NSAID therapy.
- If you have severe heart failure.
- If you are in the third trimester of pregnancy.
- If you are breast-feeding.
- If you have severe impaired liver or kidney functions.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Relifex tablets if you have any of the following conditions:

- If you have a history of gastrointestinal disease such as ulcerative colitis or Crohn's disease
- If you had stomach ulcers or inflammatory bowel disease
- If you have a serious heart condition called congestive heart failure
- If you have peripheral arterial disease (circulation problems in the limbs, usually in the legs)
- If you have hyperlipidaemia (high blood level of a type of fat called lipids)
- If you have ever had a stroke
- If you have had bleeding in the brain or other bleeding problems
- If you have diabetes
- If you are a smoker
- If you have or have ever had high blood pressure (hypertension)
- If you are a woman trying to become pregnant or undergoing investigation for infertility (see 'Pregnancy, breast-feeding and fertility' section)
- If you are over 65 years of age, you have a higher risk of getting side effects

If you are going to be treated for a long time you should have regular medical tests for side effects and kidney function.

Medicines such as Relifex tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Children

There is no information on the use of Relifex tablets in children.

You should take the lowest dose for the shortest time necessary to relieve your symptoms.

Other medicines and Relifex tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- Warfarin or heparin (blood thinners)
- Anti-hypertensives (taken to reduce blood pressure)
- Diuretics (water tablets)
- Cardiac glycosides (drugs used in the treatment of heart failure such as digoxin)
- Acetylsalicylic acid (Aspirin) use to treat pain, fever and inflammation
- Anti-platelets drugs (used to decrease blood clots forming)
- Highly protein-bound drugs (e.g. sulphonamides, sulphonylureas or hydantoin)
- Diuretics (drugs that promote the production of urine)
- Antihypertensive drugs (used to lower blood pressure)
- Quinoline (type of antibiotic)
- Tacrolimus (a drug used to prevent organ rejection)
- Zidovudine (a drug used to treat and prevent HIV/AIDS)
- Lithium (a treatment for mental illness)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and certain cancers)
- Ciclosporin (used to treat rheumatoid arthritis, psoriasis, and prevent rejection of a transplanted organ)
- Other non-steroidal anti-inflammatory drugs (NSAIDs or COX-2) including aspirin
- Corticosteroids (used to reduce inflammation, suppress the immune system or replace hormones)
- Aminoglycosides (types of antibiotics)
- Probenecid (used to treat gout)
- Oral hypoglycemic drugs (used to manage diabetes)
- Selective serotonin re-uptake inhibitors (used for depression)

It may still be all right for you to be given Relifex tablets and your doctor will be able to decide what is suitable for you.

Pregnancy, breast-feeding and fertility

You should not take Relifex tablets while pregnant or breast-feeding unless your doctor tells you to. Relifex tablets may make it more difficult to become pregnant, speak to your doctor if you are having problems.

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 machines

Dizziness and confusion have been reported after taking Relifex. If these symptoms occur, the patient must not drive or operate machinery.

3. How to take Relifex tablets

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

The recommended doses are as follows:

Adults
1 tablet (1g) or 2 x 500mg, taken as a single night time dose with or without food. For severe or persistent symptoms, or during flare ups, an extra 500mg to 1g may be given as a morning dose.

For short-term conditions such as sports injuries, 1 tablet (1g) or 2 x 500mg may be given to start with and the total dosage should not be more than 2g a day.

Use in children
Relifex tablets is not recommended for use in children.

Older people
The total daily dosage should not be more than 1g. A starting dose of 500mg should be used.

If you take more Relifex tablets than you should
Go to the accident and emergency department of your hospital immediately.

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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Stop taking Relifex tablets and contact your doctor immediately if you notice:

- Signs of stomach or intestinal bleeding, ulceration or perforation, such as: blood in your faeces (stools/motions), black tarry stools, blood or dark particles that look like coffee grounds in your vomit, or abdominal pains (pains in your stomach) or other abnormal stomach symptoms, indigestion or heartburn. Peptic ulcers (ulcer in your stomach or duodenum), or stomach or intestinal bleeding, sometimes fatal, particularly in the elderly may occur.
- Severe skin eruptions such as severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome).
- Peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis).

The following side effects have been reported:
Diarrhoea, constipation, indigestion, nausea (feeling sick), tummy pain, dry mouth, flatulence (wind), constipation, stomach ulcer, inflammation of the stomach lining, bleeding in the digestive tract, vomiting, black faeces due to a bleed from the stomach or duodenum (melaena), vomiting blood (haematemesis), retention of fluid, nose bleeds, mouth sores (stomatitis), worsening of Crohn's disease.

Also, headache, dizziness, confusion, hallucinations, nervousness, inability to sleep, drowsiness, tiredness, shortness of breath, respiratory disorder, ringing in the ear and ear disorders, abnormal vision and eye disorders, rash, hives, hair loss, abnormal bleeding in menstruation, abnormal sensations (such as pins and needles), muscle tissue disease, aseptic meningitis (a condition which the layers lining the brain become inflamed) and allergic reactions (such as anaphylaxis), have also been reported.

Low blood platelet count, low red blood cell count and increased liver enzymes (these can be detected by your doctor with a blood test), jaundice (yellow eyes and skin) and liver failure have occurred.

Red spots, severe peeling or blistering of the skin, and sensitivity to light have been reported. There have been reports of kidney side effects including kidney damage and kidney failure. A form of lung disease known as interstitial pneumonitis has been reported.

Swelling, high blood pressure, and heart failure have been reported. There may be an increased risk of heart attack or stroke.

If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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 Relifex tablets

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date (Exp) which is marked on the carton and blister strips. This refers to the last day of that month.
- Keep the tablets in the original container in order to protect from light.
- Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Relifex tablets contain
Your tablets contain the active ingredient nabumetone.
Each film-coated tablet contains 500mg nabumetone.

The other ingredients are: sodium starch glycollate, sodium lauryl sulphate, hypromellose, magnesium stearate, microcrystalline cellulose, saccharin sodium, liquid caramel flavour, red carmine (E120), iron oxide yellow (E172), titanium dioxide (E171), talc, polyethylene glycol 400, carnauba wax.

The tablet contains a sodium content of 2.5mg.

What Relifex tablets look like and contents of the pack
Your tablets are dark red, film-coated, marked "Relifex" on one side and "500" on the other.

Your medicine is available in a plastic bottle containing 56 tablets.

Manufacturer
Manufactured by: Haupt Pharma Wülfing GmbH, Bethelner Landstraße 18, 31028 Gronau, Germany.

Procured from within the EU and Repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/121/1

Leaflet revision & issue date (ref): 12.09.16

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