Package leaflet: Information for the patient

Migsun 85 mg/500 mg film-coated tablets

sumatriptan and naproxen sodium

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 Migsun is and what it is used for

Migsun contains two active substances, sumatriptan and naproxen sodium. Sumatriptan belongs to a group of medicines called triptans (also called serotonin receptor (5-HT1) agonists) and naproxen sodium belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Migsun is used to treat headache phase of migraine attacks in adult patients where treatment with sumatriptan alone is insufficient. Migsun can be used to treat migraine attacks with or without aura (aura is a premonition usually connected with flashes of light, serrated images, stars or waves).

Migraine headaches are thought to result from the dilatation of blood vessels in the head. Sumatriptan constricts these blood vessels, thus relieving the migraine headache and naproxen lessens the pain.

2. What you need to know before you take Migsun

Do not take Migsun, if you
- are allergic to sumatriptan or naproxen or any of the other ingredients of this medicine (listed in section 6)
- are allergic to or have earlier had allergic reactions (itchiness or skin rash) or asthma symptoms (wheeziness) to acetyl salicylic acid or other NSAIDs such as ibuprofen, diclofenac or meloxicam
- have or have had heart problems such as narrowing of the arteries (ischaemic heart disease), chest pain (angina pectoris), heart attack or severe heart failure
- have high blood pressure. If decided by your doctor you may be able to use Migsun if your high blood pressure is mild and is being treated.
- have had a stroke or a mini-stroke (also called a transient ischaemic attack, TIA)
- have blood circulation problems in the legs causing cramp-type pain when you walk (peripheral vascular disease)
- have or have had a gastric or duodenal ulcer
- are suffering or have ever suffered from bleeding in the stomach or intestines while taking NSAIDs

- have severely reduced kidney function
- have moderately or severely reduced liver function or active liver disease
- use other migraine medicines including those which contain ergotamine or similar medicines such as methysergide maleate or any triptans/5HT1 agonists (such as naratriptan or zolmitriptan)
- use, or have used within 2 weeks so called MAO inhibitors (e.g moclobemide for the treatment of depression or selegiline for the treatment of Parkinson's disease)
- are in your last three months of pregnancy.

Warnings and precautions
Migsun should only be used if your headache is definitely migraine. If the headache is different from your usual headaches, you should not take Migsun without first contacting your doctor.

Talk to your doctor or pharmacist before taking Migsun, if any of the following apply to you:
- blood circulation disorders in the hands and feet or brain
- pain in your chest and a feeling of pressure for a short time after you have taken Migsun. This can be quite intensive and may radiate up towards your throat. In very rare cases this may be caused by effects on your heart. Therefore, if the symptoms do not disappear, contact your doctor.
- you are at risk of developing heart disease; a heavy smoker or you are using nicotine replacement therapy (patches or chewing gum), especially if you are
  - a woman who has been through the menopause
  - a man over 40 years

  In very rare cases serious heart conditions have occurred after taking Migsun, even if no signs of any heart disease were found. Contact your doctor for advice if you have any concerns.
- coronary artery disease
- unexplained stomach pain or anaemia (low blood haemoglobin) or if you have noticed blood in your stools or your stools are black
- a gastrointestinal disease, such as ulcerative colitis (*colitis ulcerosa*) or Crohn's disease
- asthma or allergies or history of swelling of the face, lips, eyes or tongue
- rhinitis or a history of nasal polyps
- blood coagulation disorder or bleeding disorder
- epilepsy or any other disease which reduces your seizure threshold
- hypersensitive to certain antibiotics (sulphonamides)
- reduced heart, kidney or liver function
- you are an elderly person
- an autoimmune condition, such as systemic lupus erythematosus (SLE).

Children and adolescents
Do not give this medicine to children under 18 years of age because efficacy and safety of Migsun in this age group have not been established.

Other medicines and Migsun
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. In particular, tell your doctor or pharmacist if you are taking:
- other medicines for migraine containing ergotamine and triptans/5-HT1 receptor agonists. These must not be taken at the same time as Migsun (see section "Do not take Migsun"). Do not take those medicines and Migsun within 24 hours of each other.
- MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease). Migsun must not be taken within two weeks after stopping use of MAO inhibitors.
- SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors) used to treat depression. Using Migsun with these medicines can cause serotonin syndrome (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heartbeat and shaking). Tell your doctor immediately if you are affected in this way.
- acetylsalicylic acid (aspirin) and other anti-inflammatory analgesics.

- medicines that prevent blood coagulation and formation of blood clots (e.g. warfarin, heparin or clopidogrel), because concomitant use increases the risk of bleeding. Combination use should be avoided.
- methotrexate (for rheumatic and cancer diseases)
- digoxin (for heart diseases)
- lithium (for bipolar disorder). Using Migsun with lithium may cause serotonin syndrome
- certain immunosuppressive medicines (e.g. ciclosporin and tacrolimus)
- Herbal products containing St John's wort (*Hypericum perforatum*). Side effects may occur with greater frequency.

Pregnancy, breast-feeding and fertility
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.

Pregnancy
Do not take Migsun if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.
You should not take Migsun during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Migsun can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breastfeeding
Both sumatriptan and naproxen are secreted in the mother's milk. Migsun should therefore not be used during breast-feeding.

Fertility
Migsun may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you are having problem getting pregnant. Taking Migsun is not recommended if you are planning to have a baby.

Driving and using machines
Migsun or the symptoms of migraine may make you drowsy or dizzy. If you are affected, don't drive or operate machinery.

Migsun contains sodium
This medicine contains 60 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Migsun

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not use Migsun to try to prevent an attack – only use it after your migraine symptoms start.

Adults
The recommended dose for adults is one tablet as soon as you can after getting a migraine.

If your headache comes back or you only get some relief from your headache you can take a second dose two hours after the first dose. Do not take more than two doses of Migsun in a 24-hour period.

If you do not get any relief after your first dose, do not take a second dose. Talk with your healthcare professional first.

Patients with liver and kidney problems
If you have mild liver or kidney problems and you have to take Migsun, you should only take one tablet in a 24-hour period.

Use in elderly (over 65 years of age)
Migsun is not recommended for elderly over 65 years of age.

Use in children and adolescents
Migsun is not recommended for children and adolescents under 18 years of age.

Method of administration
Oral use. Tablets should be swallowed whole with water. Do not chew or crush the tablets as this can affect the optimised rate of absorption of the medicine. Tablets can be taken with or without food. Food has no significant effect on the effect of Migsun.

If you take more Migsun than you should

Do not take more than two doses of Migsun in a 24-hour period.

Overdose symptoms are the same as those listed in section 4 "Possible side effects". If you have taken more medicine than you should, or if children have taken medicine by accident, please contact your doctor or hospital to get an opinion of the risk and advice on action to be taken.

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. Some of the side effects reported may be caused by the migraine attack itself.

Important side effects to look out for:
Stop taking Migsun and tell your doctor straight away if any of the following side effects happen. You may need urgent medical treatment.

Serious stomach or gut problems, signs include:
Uncommon (*may affect up to 1 in 100 people*):
- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut. Signs include upset stomach, stomach pain, fever, feeling or being sick.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

Very rare (*may affect up to 1 in 10 000 people*):
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back.

Allergic reactions, signs include:
Rare (*may affect up to 1 in 1 000 people*):
- Severe allergic reaction with rapid onset that causes difficulty breathing or dizziness (anaphylactic reaction)

- Swelling of the face, tongue or throat, difficulty swallowing, hives and difficulty breathing (angioneurotic oedema).

Liver problems, signs include:
Rare (*may affect up to 1 in 1 000 people*):
- Feeling tired, loss of appetite, feeling or being sick (nausea, vomiting), pain or swelling in the upper right abdomen, dark coloured urine, pale coloured stools and yellowing of your skin or the whites of your eyes (toxic hepatitis).

Severe skin rashes, signs include:
Very rare (may affect up to 1 in 10 000 people):
- Usually begins with flu-like symptoms (feeling unwell, fever, headache, cough and joint pain) and followed by a red or purple rash that develops quickly, with painful blisters and peeling of your skin and possibly blisters in your mouth, throat, eyes and genital track (Stevens-Johnson syndrome/ toxic epidermal necrolysis).

Heart attack, signs include:
Not known (*frequency cannot be estimated from the available data*):
- Chest pain which may spread to your neck and shoulders and down your left arm.

Stroke, signs include:
Not known (frequency cannot be estimated from the available data):
- Muscle weakness and numbness. This may only be on one side of your body.
- A suddenly altered sense of smell, taste, hearing or vision, confusion.

Meningitis, signs include:
Very rare (*may affect up to 1 in 10 000 people*):
- Fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

Other possible side effects:

Very common (*may affect more than 1 in 10 people*):
- Upper abdominal pain.
- Feeling sick (nausea), heartburn, constipation.

Common (*may affect up to 1 in 10 people*):
- Dizziness, tingling, drowsiness, sensory disturbances, headache, light-headedness
- Visual disturbances
- Ringing in the ear, hearing disorder
- Worsening of heart failure (oedema, shortness of breath), temporary increase in blood pressure (arising soon after treatment), flushing
- Difficulty in breathing
- Being sick (nausea, vomiting), digestive disorder, diarrhoea, inflammation of the mucous membrane of mouth
- Skin symptoms (e.g. itching, rash, red spots), bruises, increased sweating
- Muscle pain
- Pain, sensation of heat or cold, pressure, tightness or heaviness, feeling of weakness, tiredness.

Uncommon (*may affect up to 1 in 100 people*):
- Increase in potassium values, fluid accumulation (oedema)
- Mood changes, depression, reduced ability to concentrate, difficulty with your memory, difficulties in sleeping or changes in your patterns of dreaming
- Seizures/epileptic fits (convulsions)
- Irregular heartbeats (palpitations)

- Increased liver enzyme and bilirubin values (jaundice)
- Menstrual disorders
- Thirst.

Rare (*may affect up to 1 in 1 000 people*):
- Hearing loss
- Fluid accumulation in the lungs
- Worsening of asthma
- Hair loss
- Skin being more sensitive to the sun, blisters and skin changes (pseudoporphyria)
- Muscle weakness, muscle pain.

Very rare (*may affect up to 1 in 10 000 people*):
- Blood problems, like anaemia, changes to the numbers of white blood cells, low platelet count, blood count abnormalities
- Worsening of Parkinson's disease
- Inflammation of the blood vessels
- Pneumonia
- Swelling of salivary glands
- Minor disturbances in liver function tests
- Skin disorder with red itchy patches usually on the palms of hands, soles of feet and face (Erythema multiforme), exacerbation of skin diseases (e.g. lichen planus, erythema nodosum, systemic lupus erythematosus (SLE)).
- Blood or proteins in urine, reduced renal function, inflammation of the kidneys (nephritis), other kidney disorders.

Not known (*frequency cannot be estimated from the available data*):
- Anxiety
- Involuntary movements (dystonia), tremor, nystagmus
- Heart problems where your heartbeat may go faster, slower or change rhythm, chest pains (angina pectoris)
- Low blood pressure, Raynaud's phenomenon (a condition where the fingers and toes become white and numb)
- Difficulties in swallowing
- Excessive sweating
- Neck stiffness, joint pain
- Pain or pain worsening at the site of injury or inflammation, fever.

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 directly via:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Migsun

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 label and carton. The expiry date refers to the last day of that month.

This medicine does 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 protect the environment.

6. Contents of the pack and other information

What Migsun contains
- The active substances are sumatriptan (as sumatriptan succinate) and naproxen sodium. Each tablet contains 119 mg sumatriptan succinate equivalent to 85 mg sumatriptan and 500 mg naproxen sodium equivalent to 457 mg naproxen.
- The other ingredients are calcium hydrogen phosphate, microcrystalline cellulose, croscarmellose sodium, sodium hydrogen carbonate, povidone, magnesium stearate, talc and coating (hypromellose, titanium dioxide (E171), triacetin, indigo carmine aluminium lake (E132)).

What Migsun looks like and contents of the pack
Migsun is a capsule-shaped, medium-blue film-coated tablet (tablet) with length, width, and thickness of 19 mm x 10 mm x 7 mm and debossed *"85/500"* on one side and plain on the other side.

Pack sizes:
Plastic container with child-resistant screw cap: 9 tablets.
Each container contains a silica gel canister desiccant and a PET coil.

Blister pack: 9 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Orion Corporation
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Orion Pharma (Ireland) Limited, c/o Allphar Services Ltd, 4045 Kingswood Road, Citywest Business Park, Co Dublin.

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