

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# MigraMax 900mg/10mg, Powder for oral solution

Acetylsalicylic acid (as DL-lysine acetylsalicylate)  
Metoclopramide hydrochloride

**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 MigraMax is and what it is used for
2. What you need to know before you take MigraMax
3. How to take MigraMax
4. Possible side effects
5. How to store MigraMax
6. Contents of the pack and other information

## 1. What MigraMax is and what it is used for

The name of your medicine is MigraMax 900mg/10mg Powder for oral solution (called MigraMax in this leaflet).

### What MigraMax contains

MigraMax contains two different medicines. These are called:

- **Metoclopramide hydrochloride** which is an antiemetic and works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting).
- **DL-lysine acetylsalicylate:** This belongs to a group of medicines called painkillers (analgesics). DL-lysine acetylsalicylate is broken down in your body to aspirin (acetylsalicylic acid). This works by blocking a substance that naturally occurs in your body called cyclo-oxygenase. Cyclo-oxygenase makes some of the chemicals that cause pain. If it is blocked, pain is relieved.

MigraMax is used in adults 18 years or older to treat the signs of migraine, such as headache, feeling sick (nausea) or being sick (vomiting).

## 2. What you need to know before you take MigraMax

**Do not take this medicine and tell your doctor if you:**

- are allergic to:
  - Metoclopramide hydrochloride
  - DL-lysine acetylsalicylate (aspirin)
  - Other salicylates or non-steroidal anti-inflammatory medicines (NSAIDs)
  - Any of the other ingredients of MigraMax (listed in section 6)

Signs of an allergic reaction can include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- have bleeding, obstruction or a tear in your stomach or gut
- have or may have a rare tumour of the adrenal gland, which sits near the kidney (pheochromocytoma)
- have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with a medicine.
- have epilepsy
- have Parkinson's disease
- are taking levodopa (a medicine for Parkinson's disease) or dopaminergic agonists (see below "Other medicines and MigraMax")
- have ever had abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency
- have a condition called mastocytosis as the use of aspirin may cause severe allergic reactions such as skin flushing, low blood pressure, a fast heartbeat and vomiting
- are under the age of 18
- have haemophilia or any other blood clotting or bleeding problems
- have an ulcer in your stomach or gut. Signs include burning or aching pain in your stomach, with an empty feeling and hunger
- have had an operation on your stomach or intestine (gut). Do not take during the first 3 to 4 days after your operation.
- have severe liver problems
- have severe kidney disease
- are pregnant. This is especially important during the third trimester (week 26 to delivery); see the Pregnancy and breast feeding section below.
- are breast feeding (see the Pregnancy and breast feeding section)

Do not give this medicine to a child less than 1 year of age (see below "Children and adolescents").

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking MigraMax

### Warnings and precautions

**Talk to your doctor, pharmacist or nurse before taking MigraMax if you:**

- have a history of abnormal heart beats (QT interval prolongation) or any other heart problems
- have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.
- are using other medicines known to affect the way your heart beats
- have any neurological (brain) problems
- have liver or kidney problems. The dose may need to be reduced (see section 3).

Your doctor may perform blood tests to check your blood pigment levels. In cases of abnormal levels (methaemoglobinemia), the treatment should be immediately and permanently stopped.

You must wait at least 6 hours between each metoclopramide dose, even in case of vomiting and rejection of the dose, in order to avoid overdose.

Do not exceed 3-month treatment because of the risk of involuntary muscle spasms.

### Children and adolescents

Uncontrollable movements (extrapyramidal disorders) may occur in children and young adults. This medicine must not be used in children below 1 year of age because of the increased risk of the uncontrollable movements (see above "Do not take this medicine and tell your doctor if you").

**Take special care with MigraMax. Check with your doctor or pharmacist before taking your medicine if you:**

- ▲ have ever had an ulcer in your stomach or gut. Signs include burning or aching pain in your stomach with an empty feeling and hunger
  - ▲ have asthma
  - ▲ have a runny nose, itching, sneezing and stuffy nose (called rhinitis)
  - ▲ have growths inside your nose causing an obstruction (called nasal polyps)
  - ▲ have gout
  - ▲ have ever had any bleeding in the stomach or intestine
  - ▲ are planning to become pregnant
  - ▲ suffer from a condition called porphyria
  - ▲ have menstrual periods which are heavier or last longer than usual
  - ▲ use an intrauterine contraceptive device (IUD)
  - ▲ drink a lot of alcohol
  - ▲ have glucose-6 phosphate dehydrogenase (G6PD) deficiency which can cause a problem with the body's red blood cells
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking MigraMax

### Other medicines and MigraMax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without prescription, including herbal medicines. This is because MigraMax can affect the way some other medicines work. Also some medicines can affect the way MigraMax works. In particular tell your doctor if you are taking any of the following:

- Levodopa or other medicines used to treat Parkinson's disease (see the section "Do not take MigraMax if you")
- anticholinergics (medicines used to relieve stomach cramps or spasms)
- morphine derivatives (medicines used to treat severe pain)
- sedative medicines
- any medicines used to treat mental health problems
- digoxin (medicine used to treat heart failure)
- ciclosporin (a medicine used to treat certain problems with the immune system)
- mivacurium and suxamethonium (medicines used to relax muscles)
- fluoxetine, paroxetine or other medicines used to treat depression
- medicines to calm or reduce anxiety (hypnotics, anxiolytics)
- medicines used for epilepsy such as phenytoin or sodium valproate
- medicines to prevent blood clotting (anti-coagulants) such as warfarin, clopidogrel, ticlopidine or dipyridamole
- Clonidine – used for high blood pressure, migraine or hot flushes in the menopause
- medicines used to treat incontinence such as oxybutynin, propiverine or tolterodine
- oral medicines used for diabetes (sulphonylureas) such as gliclazide
- sedative antihistamines such as chlorphenamine or promethazine
- Methotrexate – used to treat rheumatoid arthritis, cancer and some other conditions
- Zafirlukast – used for asthma
- antibiotics, used to treat infections
- medicines used to lower the amount of uric acid in your body (uricosurics) such as probenecid or sulfinpyrazone
- Interferon alpha – used to treat certain types of infections and certain forms of cancer
- Mifepristone – usually given in hospital for termination of a pregnancy
- water tablets (diuretics) such as spironolactone, triamterene or amiloride
- painkillers that lower inflammation (non-steroidal anti-inflammatory medicines – NSAIDs), such as ibuprofen
- medicines for indigestion and heartburn (antacids)
- steroid medicines – used for lots of different illnesses such as inflammation, allergy or immune system problems
- Nicorandil – used to treat chest pain
- Levothyroxine – used to treat thyroid problems
- Tenofovir disoproxil when taken with high doses of NSAIDs in those with kidney (renal) dysfunction
- Acetazolamide – used for glaucoma, fluid retention and some forms of epilepsy
- Varicella vaccine – used for vaccination against chicken pox. Do not take MigraMax for 6 weeks after vaccination against chicken-pox.
- Metamizole – used to prevent and treat pain and reduce fever

### Taking MigraMax with alcohol

Do not drink alcohol while taking MigraMax as it may make you feel sleepy

### Fertility, pregnancy and breast feeding

Do not take this medicine if:

- You are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before being given this medicine
  - You are breast feeding or planning to breast feed. This is because it passes into breast milk and may affect your baby.
- The product belongs to a group of medicines which may impair the fertility in women. This effect is reversible on stopping the medicine.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast feeding.

### Driving and using machines

You may feel drowsy, dizzy or have uncontrollable twitching, jerking or writhing movements and unusual muscle tone causing distortion of the body after taking this medicine. It may also affect your vision and also interfere with your ability to drive and use machines.

### MigraMax contains aspartame

This is a source of phenylalanine. It may be harmful for people with phenylketonuria.

## 3. How to take MigraMax

Always take MigraMax exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### Taking this medicine

- Take this medicine by mouth
- Pour the contents of one sachet into some water, mix well and drink straight away
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

### How much to take

#### Adults (18 years and older):

- Take one sachet when you have the first warning of a migraine attack
- If you do not feel better, you may take a second sachet 2 hours later
- Do not take more than three sachets in a 24 hour period

#### Older people

The dose may need to be reduced depending on kidney problems, liver problems and overall health. Talk to your doctor if you have with poor health, liver or kidney problems.

#### Children and adolescents

Do not take if you are under 18 years old

#### If you take more MigraMax than you should

If you take more MigraMax than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen:

- Experiencing uncontrollable movements in your body (extrapyramidal disorders)
- Drowsiness, confusion, loss of consciousness, confusion, hallucinations
- Heart problems
- Being sick (vomiting); feeling thirsty (dehydration); ringing in the ears (tinnitus); balance problems, dizziness (vertigo); loss of hearing (deafness); sweating, feeling of warmth in the hands, feet or lips with a strong and forceful pulse; increased or heavy breathing
- In some cases vomiting blood; very high body temperature; a sense of nervousness, feeling shaky or sweaty (hypoglycaemia); tiredness or weakness and muscle cramps (hypokalaemia); you may also feel that your limbs are swollen (fluid retention); this is a sign of changes in the way your kidneys are working
- Extreme shortness of breath or difficulty breathing and a feeling of suffocating or drowning. These are signs of something called non-cardiac pulmonary oedema
- You may also bleed easily or have unusual bruising or bleeding – these are signs of blood problems such as thrombocytopenia. Other effects such as lack of awareness (disorientation), confusion, loss of consciousness (coma) and rapid uncontrollable shaking (convulsion) may also occur

Your doctor may prescribe you a treatment for these side effects if necessary.

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

## 4. Possible side effects

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

### Stop taking MigraMax and see a doctor or go to a hospital straight away if you:

- experience uncontrollable movements of the body (often involving the head or neck). These may occur in children or young adults and particularly when high doses are used. These signs usually occur at the beginning of treatment and may even occur after one single administration. These movements will stop when treated appropriately.
- have a high fever, high blood pressure, convulsions, sweating, over-production of saliva. These may be signs of a condition called neuroleptic malignant syndrome.
- have itching or skin rashes, swelling of the face, lips or throat, difficulty in breathing. These may be signs of an allergic reaction, which may be severe.

#### Very common (may affect more than 1 in 10 people)

- feeling drowsy.

#### Common (may affect up to 1 in 10 people)

- depression
- uncontrollable movements such as tics, shaking, twisting movements or muscle contractions causing stiffness and rigidity
- symptoms similar to Parkinson disease (rigidity, tremor)
- feel restless
- blood pressure decrease (particularly with intravenous route)
- diarrhoea, flatulence, nausea, heartburn, bloating, vomiting
- feeling weak, tired, dizzy or having pale skin (anaemia)

#### Uncommon (may affect up to 1 in 100 people)

- raised levels of a hormone called prolactin in the blood which may cause milk production in men and women who are not breast-feeding
- irregular periods
- hallucinations
- decreased levels of consciousness
- abnormal muscle movement
- low blood pressure
- slow heartbeat (particularly with intravenous route)
- allergic reactions (hypersensitivity)

#### Rare (may affect up to 1 in 1,000 people)

- confusion
- convulsions/fits (especially in patients with epilepsy)

#### Very rare (may affect 1 in 10,000 people)

- difficulty breathing, wheezing or tightness in the chest (called bronchospasm)
- an itchy, lumpy rash sometimes called hives (urticaria)

#### Not known (frequency cannot be estimated from the available data)

- abnormal blood pigment levels which may change the colour of your skin
- liver problems
- blood problems causing you to bruise or bleed more easily or to get more infections than usual
- abnormal development of breasts (gynaecomastia)
- involuntary muscle spasms after prolonged use, particularly in elderly patients
- high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome
- changes in heartbeat, which may be shown on an ECG test
- cardiac arrest (particularly with injection route)
- coughing up blood and having difficulty breathing
- black tarry stools (faeces) or blood in the stools
- blood or dark particles (coffee ground colour) when you are being sick
- a burning, aching pain in your stomach, with an empty feeling and hunger. You may have an ulcer in your stomach or gut
- severe pain in your stomach or intestines
- shock (severe decrease of heart pressure) (particularly with injection route)
- fainting (particularly with intravenous route)
- allergic reactions which may be severe (particularly with intravenous route)
- very high blood pressure
- a sudden severe headache which could be a sign of bleeding on the brain (especially in the elderly)
- changes in your menstrual cycle
- pain when passing urine with lower back pain, sometimes radiating to the sides and/or groin. These could be signs of kidney stones
- serious skin blisters or a rash
- feeling nervous (anxious), restless or confused
- difficulty sleeping
- feeling dizzy or having ringing in your ears (tinnitus)
- feeling nervous (anxious), restless or confused
- difficulty sleeping

Talk to your doctor or pharmacist if any of the side effects get serious or lasts longer than a few days, or if you notice side effects not listed in this leaflet

#### 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 the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store MigraMax

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 after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

## 6. Contents of the pack and other information

### What MigraMax contains

- Each sachet contains 1620mg DL-lysine acetylsalicylate equivalent to 900mg acetylsalicylic acid (the same amount that is in three 300mg aspirin tablets) and 10mg metoclopramide hydrochloride (as anhydrous) as the active ingredients
- MigraMax sachets also contain aspartame, glycine and lemon flavour

### What MigraMax looks like and contents of the pack

MigraMax is a white powder with a lemon odour and is soluble in water

MigraMax is available in cartons containing 2, 6 or 20 sachets. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK.

#### Manufacturer

Sanofi Winthrop Industrie, 196 avenue du Maréchal Juin, 45200 Amilly, France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

**This leaflet was last revised in December 2021**

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