

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S2

### **MIGREX<sup>®</sup> 50 (tablets)**

Sumatriptan

Contains sugar (lactose monohydrate 185,48 mg per tablet)

#### **Read all of this leaflet carefully before you start taking MIGREX 50**

- Keep this leaflet. You may need to read it again.
- Do not share MIGREX 50 with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

#### **What is in this leaflet**

1. What MIGREX 50 is and what it is used for
2. What you need to know before you take MIGREX 50
3. How to take MIGREX 50
4. Possible side effects
5. How to store MIGREX 50
6. Contents of the pack and other information

#### **1. What MIGREX 50 is and what it is used for**

MIGREX 50 belongs to a group of medicines called triptans (also known as 5-HT<sub>1</sub> receptor agonists).

MIGREX 50 tablets are indicated for the acute (immediate) relief of migraine attacks, in patients previously diagnosed by a medical practitioner and initiated on treatment with sumatriptan.

## **2. What you need to know before you take MIGREX 50**

### **Do not take MIGREX 50:**

- If you are hypersensitive (allergic) to sumatriptan or any of the other ingredients of MIGREX 50 (listed in section 6).
- If you have a heart problem such as narrowing of the arteries (ischaemic heart disease), or chest pains (Prinzmetal's angina / coronary vasospasm), or have had a heart attack.
- If you have circulation problems in your legs that cause cramp-like pains when you walk (peripheral vascular disease),
- If you have had a stroke or a mini-stroke (also called a transient ischaemic attack or TIA).
- If you have serious liver disease.
- If you have uncontrolled high blood pressure (hypertension).
- Together with other migraine medicines, including ergotamine containing preparations or similar medicines such as methysergide, or any other triptan or 5HT<sub>1</sub> agonist.
- Together with monoamine oxidase inhibitors (MAOI) (a type of antidepressant). Do not use MIGREX 50 within two weeks of discontinuation of MAOI therapy.

### **Warnings and precautions**

#### **Take special care with MIGREX 50:**

- If you feel chest pain and tightness, which may be intense and involve the throat. These effects may be intense, but they usually pass quickly. If they don't pass quickly, or they become severe, get medical help immediately.
- In very rare cases, people have developed serious heart conditions after using MIGREX 50, even though they had no signs of heart disease before. If any of the points below apply to you it could mean you have a greater risk of developing heart

disease. Tell your doctor so that your heart function can be checked before you take

**MIGREX 50:**

- If you are a heavy smoker, or using nicotine replacement therapy.
- If you are a woman who has been through the menopause or a man over 40 years.
- If you have high blood pressure.
- If you are taking anti-depressants called SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors).
- If you have a history of fits (seizures) or if you have other conditions which might make it more likely that you'll have a fit.
- If you have a known allergy (hypersensitivity) to sulphonamides (a type of antibiotic). Hypersensitivity reactions may range from cutaneous (skin) hypersensitivity to anaphylaxis (a sudden life-threatening allergic reaction with sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing).
- If you have liver or kidney disease.
- If you use MIGREX 50 frequently. Using MIGREX 50 too often may make your headache worse.

**Children (under 18 years of age) and patients over 65 years:**

Experience of the use of MIGREX 50 in children (under 18 years of age) and patients over 65 years is limited and as such, the use of MIGREX 50 in these age groups is not recommended.

**Other medicines and MIGREX 50:**

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

You must tell your doctor if you are taking:

- Ergotamine, which is also used to treat migraine, or similar medicines such as, methysergide. Do not use MIGREX 50 at the same time as these medicines. Stop taking these medicines at least 24 hours before using MIGREX 50. Do not take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using MIGREX 50.
- Other triptans / 5-HT<sub>1</sub> receptor agonists, also used to treat migraine. Do not use MIGREX 50 at the same time as these medicines. Stop taking these medicines at least 24 hours before using MIGREX 50. Do not take another triptan / 5-HT<sub>1</sub> receptor agonist again for at least 24 hours after using MIGREX 50.
- Antidepressants known as Monoamine Oxidase Inhibitors (MAOIs). Do not use MIGREX 50 if you have taken these in the last 2 weeks.
- Anti-depressants called SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors). Using MIGREX 50 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.
- St. John's Wort (*Hypericum perforatum*). Taking herbal remedies that contain St. John's Wort together with MIGREX 50 may make side effects more likely.

### **Pregnancy, breastfeeding and fertility**

Safety in pregnancy has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Do not breastfeed your baby for 12 hours after using MIGREX 50. If you express any breast milk during this time, discard the milk and don't give it to your baby.

### **Driving and using machines**

Drowsiness may occur as a result of migraine or treatment with MIGREX 50. This may influence the ability to drive and to operate machinery.

### **MIGREX 50 contains lactose**

MIGREX 50 contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take MIGREX 50.

### **3. How to take MIGREX 50**

Do not share medicines prescribed for you with others.

Always take MIGREX 50 exactly as your doctor has told you. Check with your doctor if you are not sure.

**MIGREX 50 SHOULD NOT BE USED PROPHYLACTICALLY.**

The recommended dose of MIGREX 50 should not be exceeded.

It is recommended that MIGREX 50 be taken as early as possible after the onset (beginning) of migraine, however it is equally effective at whatever stage of the attack it is taken.

The recommended dose for initial therapy is 50 mg (1 tablet), depending on response this may be increased to 100 mg (2 tablets).

If symptoms start to come back, you can take another dose (1 or 2 tablets) of MIGREX 50, provided that there is a minimum interval of two hours between doses. Do not take more than 300 mg (6 x 50 mg tablets) in any 24 hour period.

If the first dose did not have a beneficial effect on the migraine, do not take a second dose for the same attack.

The tablet should be swallowed whole with water.

The dose of sumatriptan should be reduced in patients with impaired liver function.

#### **If you take more MIGREX 50 than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

#### **4. Possible side effects**

MIGREX 50 can have side effects.

Not all side effects reported for MIGREX 50 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MIGREX 50, please consult your health care provider for advice.

If any of the following happens, stop taking MIGREX 50 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to MIGREX 50. You may need urgent medical attention or hospitalisation.

#### **Frequent side effects:**

- Pain, heaviness, pressure or tightness, sensations of tingling, numbness, heat or cold.  
These symptoms usually pass quickly, may be intense and can affect any part of the body including the throat and chest
- Decreased sensitivity (particularly to touch)
- Flushing
- Dizziness
- Feelings of weakness
- Fatigue (feeling tired)
- Drowsiness
- Breathing difficulty
- Nausea (feeling sick) and vomiting (being sick)
- Increases in blood pressure, which come and go
- Muscle pain

**Less frequent side effects:**

- Disturbances in liver function tests have been observed

**The frequency of the following side effects are unknown:**

- Seizures (fits)
- Tremors (uncontrollable shaking)
- Uncontrollable muscle spasms and twitching (dystonia)
- Rapid and uncontrollable movement of the eyes
- Aura or a blind spot that obstructs part of your vision
- Visual disturbances such as flickering, reduced vision, double vision, loss of vision, and in some cases even permanent defects (although these may be due to the migraine attack itself)
- Bradycardia (slow heartbeat)
- Tachycardia (fast heartbeat)

- Palpitations (your heart feels like it has skipped a beat or added an extra beat)
- Cardiac arrhythmias (irregular heartbeat)
- Transient ischaemic ECG changes (changes in the electrical activity of your heart, which will be shown in an 'ECG' test)
- Myocardial infarction (heart attack)
- Chest-pain (caused by angina or coronary artery vasospasm)
- Circulation problems in the legs with cramp-like pains when walking (peripheral vascular resistance)
- Hypotension
- Pale, blue-tinged skin and/or pain in your fingers, toes, ears, nose or jaw in response to cold or stress (Raynaud's phenomenon)
- Pain in the lower left side of the stomach and bloody diarrhoea (ischaemic colitis)
- Diarrhoea
- Difficulty with swallowing
- Stiff neck
- Pain in the joints
- Feeling anxious
- Excessive sweating
- Pain trauma activated
- Pain inflammation activated

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under

SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MIGREX 50.

Suspected side effects can also be reported directly to the HCR via [Patientsafety.sacg@novartis.com](mailto:Patientsafety.sacg@novartis.com).

## **5. How to store MIGREX 50**

Store at or below 25 °C.

Keep the blisters in the carton until required for use.

### **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

Any unused medicines should be returned to your doctor, pharmacist, or health care professional for disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What MIGREX 50 contains**

The active substance is 50 mg sumatriptan base as the succinate salt.

### **The other ingredients are:**

91 Parts ammonio methacrylate copolymer type A and 9 parts carboxymethylcellulose sodium

Croscarmellose sodium

Ferric oxide red (E 172)

Ferric oxide yellow (E 172)

Grapefruit flavour

Lactose monohydrate

Magnesium stearate

Microcrystalline cellulose

### **What MIGREX 50 looks like and contents of the pack**

Oblong, breaking notch on both sides, pink with partly pink dots

MIGREX 50 tablets are packed in aluminium / aluminium foil blister packs, containing two tablets. The blisters are packed into a cardboard carton, together with the leaflet.

**Holder of Certificate of Registration**

Sandoz SA (Pty) Ltd<sup>1</sup>

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**Access to the corresponding Professional Information**

Not applicable.

<sup>1</sup>Company Reg. No.: 1990/001979/07