PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

MIGREX® OTC (tablets)

Sumatriptan

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

Read all of this leaflet carefully before you start taking MIGREX OTC

- Keep this leaflet. You may need to read it again.
- Do not share MIGREX OTC 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 OTC is and what it is used for

2. What you need to know before you take MIGREX OTC

3. How to take MIGREX OTC

4. Possible side effects

5. How to store MIGREX OTC

6. Contents of the pack and other information

1. What MIGREX OTC is and what it is used for

MIGREX OTC belongs to a group of medicines called triptans (also known as 5-HT_1 receptor agonists).

MIGREX OTC 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 OTC

Do not take MIGREX OTC:

- If you are hypersensitive (allergic) to sumatriptan or any of the other ingredients of MIGREX OTC (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 any disease or condition resulting in reduced blood flow to parts of the brain or 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 $5HT_1$ agonist.
- Together with monoamine oxidase inhibitors (MAOIs) (a type of antidepressant). Do not use MIGREX OTC within two weeks of discontinuation of MAOI therapy.

Warnings and precautions

Take special care with MIGREX OTC:

- 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 OTC, 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 OTC:

- 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 OTC frequently. Using MIGREX OTC too often may make your headache worse.

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

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

Other medicines and MIGREX OTC:

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 OTC at the same time as these medicines. Stop taking these medicines at least 24 hours before using MIGREX OTC. Do not take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using MIGREX OTC.
- Other triptans / 5-HT_1 receptor agonists, also used to treat migraine. Do not use MIGREX OTC at the same time as these medicines. Stop taking these medicines at least 24 hours before using MIGREX OTC. Do not take another triptan / 5-HT_1 receptor agonist again for at least 24 hours after using MIGREX OTC.
- Antidepressants known as Monoamine Oxidase Inhibitors (MAOIs). Do not use MIGREX OTC 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 OTC 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 OTC 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 OTC. 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 OTC. This may influence the ability to drive and to operate machinery.

MIGREX OTC contains lactose

MIGREX OTC 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 OTC.

3. How to take MIGREX OTC

Do not share medicines prescribed for you with others.

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

MIGREX OTC SHOULD NOT BE USED PROPHYLACTICALLY.

The recommended dose of MIGREX OTC should not be exceeded.
It is recommended that MIGREX OTC 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 OTC, 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 OTC 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 OTC can have side effects.

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

If any of the following happens, stop taking MIGREX OTC 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 OTC. 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 OTC.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store MIGREX OTC

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 OTC 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 OTC looks like and contents of the pack

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

MIGREX OTC 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[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

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Access to the corresponding Professional Information

Not applicable.

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