

This medicine can be sold with a physician's prescription only

SUMATRIDEX® 50, 100, Caplets

Each caplet contains Sumatriptan (as succinate) at a dosage of 50 or 100 mg respectively.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and section 2 "Important information about some of the ingredients of the medicine"

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It might harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Sumatriptan is used for the acute relief of migraine attacks, with or without aura. Sumatriptan should only be used where there is a clear diagnosis of migraine.

Therapeutic group: Analgesics: triptans - selective 5-HT₁ receptor agonists.

Migraine symptoms may be caused by the temporary dilation of blood vessels in the head. Sumatriptan is believed to reduce the dilation of these blood vessels. This in itself helps to relieve the headache and ease other symptoms of a migraine attack, such as nausea or vomiting and sensitivity to light and sound.

2. Before using the medicine

Do not use the medicine:

- If you are hypersensitive (allergic) to the active ingredient sumatriptan or to any of the additional ingredients the medicine contains (see section 6).
- If you have a heart problem such as arterial stenosis (ischaemic heart disease) or chest pains (angina), or if you have had a heart attack.
- If you have circulation problems in your legs, which 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 high blood pressure. You may be able to use Sumatriptan if your high blood pressure is mild and is being treated.
- If you have a serious liver disease.
- With other migraine medicines, including those which contain ergotamine, or similar medicines such as methysergide maleate; or any triptan or 5-HT₁ agonist (such as naratriptan or zolmitriptan).
 - with any of the following anti-depressant medicines: monoamine oxidase inhibitors (MAOIs) or if you have taken a MAOI in the last 2 weeks.

If any of these apply to you
→ tell your doctor and do not use Sumatriptan.

Special warnings regarding the use of the medicine

Before treatment with Sumatriptan, tell the doctor:

- if you have any additional risk factors
- if you are a heavy smoker, or are using nicotine replacement therapy, and especially
- if you are a man over the age of 40, or
- if you are a post-menopausal woman

In very rare cases, people have developed serious heart problems after using sumatriptan, even though they had no signs of heart disease before. If any of the points above applies to you, you may have a greater risk of developing heart disease, therefore:

→ Tell your doctor so that your heart function can be checked before Sumatriptan is prescribed for you.

If you have a history of fits (seizures) or if you have other conditions which might make it more likely that you'll have an attack – for example, a head injury or alcoholism:

→ Tell your doctor so that you can be supervised more closely.

If you have had high blood pressure, Sumatriptan may not be suitable for you

→ Tell your doctor before using Sumatriptan.

If you have liver or kidney disease

If any of these apply to you:

→ Tell the doctor before using Sumatriptan.

If you are allergic to antibiotics called sulphonamides

If so, you may also be allergic to Sumatriptan. If you know you are allergic to an antibiotic but you are not sure whether it is a sulphonamide:

→ Tell your doctor or pharmacist before using Sumatriptan.

If you are taking anti-depressant medicines called SSRIs

(Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin and Noradrenaline Reuptake Inhibitors), or TCAs (Tricyclic Anti-depressants):

→ Tell your doctor or pharmacist before using Sumatriptan. See also section "Drug interactions" below.

If you use Sumatriptan frequently.

Using Sumatriptan too often may worsen your headaches.

→ Tell your doctor if this applies to you. Your doctor may recommend you stop using Sumatriptan.

If you feel pain or tightness in your chest after you use Sumatriptan

These effects may be intense but they usually pass quickly. If they do not pass quickly, or they worsen:

→ Seek medical assistance immediately. Section 4 (appears below) includes additional information about these possible side effects.

Drug interactions

Some medicines must not be taken with Sumatriptan and others may cause side

effects if they are taken with Sumatriptan.

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Ergotamine, which is also used to treat migraine, or similar medicines, such as methysergide (see section 2 "Do not use the medicine"). Do not use Sumatriptan concomitantly with these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan. Do not take any medicine which contains ergotamine or compounds similar to ergotamine again for at least 6 hours after using Sumatriptan.
- Other triptans/5-HT₁ receptor agonists (such as naratriptan, rizatriptan or zolmitriptan), which are also used to treat migraine (see section 2 "Do not use the medicine"). Do not use Sumatriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan. Do not take another triptan/5-HT₁ receptor agonist again for at least 24 hours after using Sumatriptan.

MAOIs, used to treat depression. If you have taken these in the last two weeks, do not use Sumatriptan.

SSRIs, SNRIs, and TCA (Tricyclic Anti-depressant) medicines used to treat depression. Using Sumatriptan together with these medicines can cause serotonin syndrome (a collection of symptoms which may include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increase of heartbeat and shaking). Tell your doctor immediately if you are affected in this manner.

Hypericum perforatum (St John's Wort). Taking herbal remedies that contain hypericum together with Sumatriptan may raise the probability of side effects.

Pregnancy, breastfeeding and fertility

If you are pregnant, think you may be pregnant or are planning to become pregnant, consult the doctor before using the medicine. There is only limited information on the safety of Sumatriptan in pregnant women, though up until now there is no evidence of any increased risk of birth defects. Your doctor will discuss with you whether or not you should use Sumatriptan while you are pregnant.

Do not breastfeed your baby for 12 hours after using Sumatriptan. If you express breast milk during this time period, discard the milk and do not give it to your baby.

Driving and using machines

Either this medicine or the migraine symptoms may cause drowsiness. **If you are affected, do not drive or operate machinery.**

Important information about some of the ingredients of this medicine

This medicine contains lactose. If you have been previously told by a doctor that you have intolerance to certain sugars, consult the doctor before starting treatment with this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per caplet, i.e. it is essentially "sodium-free".

3. How to use this medicine

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure about the dosage and the manner of treatment with the medicine.

When to take Sumatriptan

- It is preferable to take Sumatriptan as soon as you feel a migraine coming on, although you can take it at any time during an attack.
- Do not use Sumatriptan to try to prevent an attack - only use it after your migraine symptoms start.

The dosage and manner of treatment will be determined only by the doctor. The usual dosage is:

- Adults aged 18 to 65
- The usual dosage for adults aged 18 to 65 is one Sumatriptan 50 mg caplet. Some patients may require a 100 mg dose - you should follow your doctor's recommendation.

Children under the age of 18

- Sumatriptan is not intended for use in children under the age of 18 years.

Elderly (aged over 65)

- Sumatriptan is not intended for use in people over the age of 65.

Do not exceed the recommended dose.

If your symptoms start to return

- You can take a second Sumatriptan caplet if at least two hours have passed since the first caplet. Do not take more than a total of 300 mg in 24 hours.

If the first caplet has had no effect

- Do not take a second caplet or any other sumatriptan preparation for the same attack. Sumatriptan can still be used for your next attack.

If Sumatriptan did not relieve you at all:

→ Refer to your doctor or pharmacist for advice.

Method of administration

Swallow the caplet whole with water. Do not halve the caplet as there is no score line. There is no information regarding crushing or chewing.

If you have accidentally taken a higher dosage

- Do not take more than six 50 mg caplets or three 100 mg caplets (that is a total of 300 mg) in 24 hours.

Taking too much Sumatriptan could make you ill. If you have taken more than 300 mg in 24 hours:

→ Refer to your doctor for advice.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Continue with the treatment as recommended by the doctor

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions on the

use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like all medicines, the use of Sumatriptan may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not experience any of them. Some of the symptoms may be caused by the migraine itself.

Allergic reaction: refer to the doctor for assistance immediately

The following side effects have occurred but their exact frequency is unknown.

- The signs of allergy include rash, hives (itchy rash); wheezing; swollen eyelids, face or lips; complete systems collapse.

If you experience any of these symptoms shortly after using Sumatriptan:

→ Do not use the medicine anymore. Refer to a doctor immediately.

Additional side effects

Common side effects (effects that appear in 1-10 out of 100 users):

- Pain, heaviness, pressure or tightness in the chest, throat or other parts of the body, or unusual sensations including numbness, tingling and warmth or cold. These effects may be intense but usually pass quickly.

If these effects continue or worsen (especially the chest pain):

→ Seek medical assistance urgently. In a very small number of people these symptoms can be caused by heart attack.

Other common side effects include:

- Nausea or vomiting, although this may be due to the migraine itself
- Tiredness or drowsiness
- Dizziness, feeling weak, or hot flushes
- Temporary increase in blood pressure
- Shortness of breath
- Aching muscles.

Very rare side effects (effects that appear in less than 1 out of 10,000 users)

- Liver function changes. If you have a blood test to check your liver function, tell your doctor that you are taking Sumatriptan.

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- Seizures/fits, tremors, muscle spasm, neck stiffness
- Visual disturbances such as flickering, reduced vision, double vision, loss of vision and in some cases even irreversible vision impairment (although these may be due to the migraine attack itself)
- Heart problems, where your heartbeat may be faster, slower or change rhythm, chest pains (angina) or heart attack
- Pale, blue-tinged skin and/or pain in your fingers and toes, ears, nose or jaw in response to cold or stress (Raynaud's phenomenon)
- Feeling faint (blood pressure may decrease)
- Pain in the lower left side of the stomach and bloody diarrhoea (ischaemic colitis)
- Diarrhoea
- If you recently had an injury or if you have an inflammation (like rheumatism or inflammation of the colon) you may experience pain or worsening of pain at the site of injury or inflammation

- Pain in the joints
- Feeling anxious
- Difficulty swallowing
- Excessive sweating

If a side effect appears, if one of the side effects worsens or when you suffer from a side effect not mentioned in this leaflet consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link

"דיווח על תופעות לוואי עקב טיפול תרופות" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.

• Storage conditions: store below 25°C.

6. Additional information

In addition to the active ingredient the medicine also contains:

Lactose monohydrate, microcrystalline cellulose, acesulfame potassium, croscarmellose sodium, magnesium stearate, silica colloidal anhydrous.

What the medicine looks like and content of the package:

Sumatriptan 50: white caplets with "50" imprinted on one side.

Sumatriptan 100: white caplets with "100" imprinted on one side.

Approved package sizes: 2, 3, 6, 7, 9, 10, 12, 14, 18, 20, 24, 28, 30, 48 caplets. Not all package sizes may be marketed.

Revised in January 2021 according to MOH guidelines.

Drug registration numbers at the national drug registry of the Ministry of Health:

Sumatriptan 50: 131-30-30966-00

Sumatriptan 100: 131-31-30967-00

Sumatriptan 50, 100, caps PIL PB1120-10

Manufacturer and registration holder:

Dexcel® Ltd.

1 Dexcel St., Or Akiva 306000, Israel