

PATIENT INFORMATION LEAFLET

Suvalan® 50 mg or 100 mg Film Coated Tablets

Sumatriptan (as succinate)

WHAT YOU SHOULD KNOW ABOUT SUVALAN TABLETS

This leaflet only talks about Suvalan Tablets. Please read it carefully before you start to take your medicine. It tells you the main points about the medicine. For more information or advice ask your doctor or pharmacist.

THE NAME OF YOUR MEDICINE

The name of your medicine is Suvalan 50mg or 100mg Film Coated Tablets.

WHAT IS IN YOUR MEDICINE?

Suvalan Tablets contain the active ingredient sumatriptan (as the succinate salt). The tablets are available in two strengths containing either 50mg or 100mg of sumatriptan. The other ingredients are: lactose (anhydrous and/or monohydrate), microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose and titanium dioxide (E171). The 50 mg tablets also contain red iron oxide (E172) and triacetin.

Suvalan tablets are available in packs of 2 or 6 film coated tablets.

HOW YOUR MEDICINE WORKS

Suvalan belongs to a group of medicines known as 5HT¹ receptor agonists. The headache of migraine is believed to be caused by painful inflammation and widening of the blood vessels in the head. Suvalan may relieve migraine both by narrowing the vessels and by acting on the nerves supplying them.

WHO MAKES YOUR MEDICINE?

Suvalan tablets are manufactured by Glaxo Operations UK Ltd., Priory Street, Ware, Hertfordshire, UK. The product authorisation is held by GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, CityWest Business Campus, Dublin 24.

WHAT ARE SUVALAN TABLETS USED FOR?

Your doctor has chosen this medicine to suit you and your condition. Suvalan tablets are used to treat migraine attacks.

BEFORE YOU TAKE YOUR MEDICINE

If you answer “**Yes**” to any of the following questions, tell your doctor about this before taking this medicine as it may not be suitable for you.

- Is this headache any different from your usual migraine attacks?
- Have you been told that you are allergic to Suvalan, sumatriptan or any of the other ingredients in Suvalan tablets?
- Are you allergic to sulphonamide antibiotics? If you are allergic to an antibiotic but you are not sure if it belongs to this group check with your doctor or pharmacist.
- Do you have ischaemic colitis?
- Do you suffer from unexpected shortness of breath, or from pain or tightness in the chest (which may or may not spread to your jaw or upper arms)?
- Have you ever had a heart attack?
- Do you have high blood pressure?
- Do you have any heart disease or suffer from angina?
- Have you had, or been told that you may have had, a stroke?
- Do you suffer from Raynaud’s disease, peripheral vascular disease (pain at the back of the legs) or are prone to cold, tingling, or numb hands and feet?
- Have you been told that you may have an increased risk of heart disease? You may be considered to have an increased risk of heart disease if you are a man over 40 a woman who has been through the menopause (change of life), have diabetes, a high blood cholesterol, are overweight or smoke. Also you may have an increased risk of heart disease if blood relatives have suffered from heart disease.
- Do you have liver or kidney disease?
- Have you had seizures or fits in the past or been told that you are prone to this problem?
- Do you have diabetes?
- Are you pregnant, or trying to become pregnant?
- Are you breast-feeding?
- Are you under 18 or over 65?

- Are you taking, any medicines for your migraine which contain ergotamine or dihydroergotamine? – If so, you must not use Suvalan preparations at the same time.
- Are you taking or have you taken any antidepressants within the past two weeks, particularly those which contain monoamine oxidase inhibitors or selective serotonin re-uptake inhibitors (SSRIs)? If so, you must not use Suvalan preparations.

Make sure that your doctor knows what other medicines you are taking or have recently taken. Remember to include all medicines, herbal remedies such as St. John's wort (*Hypericum perforatum*), or dietary supplements, such as vitamins, iron or calcium, which you have bought yourself.

Suvalan or your migraine itself may make you drowsy so you should not drive or operate machinery if you are affected.

If you are not sure why this medicine has been prescribed for you, ask your doctor.

HOW TO TAKE SUVALAN TABLETS

Suvalan tablets should only be used after the onset of a migraine attack. Do not use Suvalan tablets to try and prevent the onset of a migraine.

Take your medicine as your doctor has told you. The label on it will usually tell you how many to take and how often. If you are not sure ask your doctor or pharmacist.

This medicine is not suitable for children (under 18 years) or elderly patients (over 65 years).

The recommended adult dose of Suvalan is one 50mg tablet, to be swallowed whole with water, as soon as the symptoms of your migraine appear although they may be taken at any time during a migraine attack. Some people may require one 100mg tablet, your doctor will tell you which dose to take. Most people find their migraine is beginning to get better within 30 minutes to one hour of having taken a Suvalan tablet.

If the symptoms come back further tablets may be taken. Do not take more than a total dose of 300 mg (six 50 mg tablets or three 100 mg tablets in 24 hours).

If your first dose has not given you any relief, do not take any more tablets for that attack.

You may take your usual pain relief medication provided it does not contain ergotamine or dihydroergotamine.

You must wait at least six hours before taking any ergotamine or dihydroergotamine containing preparations. If you are unsure about any medicines you are taking, ask your doctor or pharmacist.

Do not take Suvalan for at least 24 hours after you have taken any medicines that contain ergotamine or dihydroergotamine.

The recommended doses of Suvalan Tablets should not be exceeded.

If you have any difficulties or do not understand the instructions ask your doctor or pharmacist.

WHAT TO DO IF YOU TAKE TOO MANY

It is important to keep to the recommended dose. Taking more than this could make you ill. If you accidentally take too many tablets, DO NOT DELAY, contact your doctor or contact your nearest hospital emergency department. Take this leaflet, or your medicine, with you so that the hospital will know what you have taken.

AFTER TAKING YOUR MEDICINE

Most people taking this medicine find that it caused no problems. As with all medicines, a few may find that it causes side effects.

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking Suvalan tablets, DO NOT take another dose and tell your doctor immediately.

- Sudden wheeziness and chest pain or chest tightness.
- Swelling of eyelids, face, lips, mouth or tongue.
- Seizures/fits.
- Lumpy skin rash or "hives" anywhere on the body.

- Lower abdominal pain and/or severe rectal bleeding.

Some people experience pain or tightness in the chest or throat when taking Suvalan tablets. If this happens to you, then discuss it with your doctor before taking any more Suvalan tablets. If the chest pain is severe or does not go away, call your doctor immediately. In very rare cases, intense chest symptoms following the taking of Suvalan tablets have been associated with heart attack.

A few people may experience pain or feelings of tingling, heat, heaviness, pressure or tightness in any part of the body after treatment with Suvalan. These symptoms may be intense but generally pass off quickly. If the symptoms persist and are severe tell your doctor immediately.

There is no need to stop taking your medicine, but tell your doctor next time you visit if you experience any of the following:

- Tiredness or sleepiness.
- Dizziness or feeling light-headed.
- Unusually slow or fast heartbeats or a feeling of irregular and/or forceful heartbeats.
- Feelings of weakness.
- Feeling sick and vomiting when not part of a migraine attack.
- Flushing (redness of the face for a short time).
- Visual disturbances.
- Loss of normal colouration in the fingers and toes. (However, if you have persistent purple discolouration of hands and feet, you should stop your medicine and consult your doctor immediately).
- Shaking or tremors.
- Uncontrolled movements.

If you have a blood test to check how your liver is functioning and you have taken Suvalan tablets, tell your doctor as they may affect the results.

If you feel unwell in any other way or have any other symptoms that you do not understand, tell your doctor or pharmacist.

STORING YOUR MEDICINE

Do not use Suvalan tablets after the expiry date printed on the carton or the foil strip. Do not store above 30°C. Store the tablets in the original pack. Keep your medicine where children cannot see or reach it. It may harm them. If your doctor stops your treatments, do not keep any leftover tablets unless your doctor tells you to. Return any leftover tablets to your pharmacist for safe disposal.

REMEMBER

This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours. As there is a genetic disposition to migraine other members of your family may also suffer from this condition. Do not under any circumstances give your Suvalan tablets to another member of your family. Suvalan is available only on prescription from a doctor. Other migraine sufferers should consult their own doctor for appropriate treatment if their condition is not adequately controlled by their current medication.

FURTHER INFORMATION

This leaflet does not contain all the information about your medicine. If you have any other questions or are not sure about anything, ask your doctor or pharmacist who has the information you need and will advise you. Alternatively, the Migraine Association of Ireland would be happy to try to answer some of these issues for you. You can telephone the 8064122, or write to them at: Senior House, All Hallows College, Gracepark Road, Drumcondra, Dublin 9.

YOU MAY NEED TO READ THIS LEAFLET AGAIN, PLEASE DO NOT THROW IT AWAY UNTIL YOU HAVE FINISHED YOUR MEDICINE.

Suvalan is a registered trademark of the GlaxoSmithKline group of companies.
PA 678/108/1 & 678/108/2

DATE OF LAST REVISION

July 2015