Frovatriptan 2.5mg Film-coated Tablets

frovatriptan

Your medicine is known by the above name but will be referred to as Frovatriptan throughout this leaflet.

Package leaflet: Information for the user

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

1) What Frovatriptan is and what it is used for

Frovatriptan 2.5 mg Film-coated Tablets contain frovatriptan (as succinate monohydrate), an anti-migraine treatment belonging to the class of triptans (5- hydroxytryptamine (5HT1) selective receptor agonists).
Frovatriptan is a medicine for the treatment of the headache phase of a migraine attack with or without aura (a temporary strange feeling before a migraine, which varies from person to person but can affect, for example, vision, smell, hearing).
Frovatriptan should not be used to prevent a migraine attack.
Frovatriptan is used to treat migraine attacks in adults.

2) What you need to know before you take Frovatriptan

The diagnosis of migraine must have been clearly established by your doctor.

Do not take Frovatriptan:
- if you are allergic to frovatriptan, or any of the other ingredients of this medicine (listed in section 6).
- if you have had a heart attack, or suffer or have suffered from certain cardiovascular diseases such as angina pectoris (characterised by crushing pain in the chest which can extend into the left arm), or circulation disorders of the legs or arms (especially in the fingers and toes).
- if you have had a stroke or a transient ischaemic attack (TIA).
- if you have severely or moderately high blood pressure, or if your blood pressure is not adequately controlled. if you have severe liver disease.
- in combination with certain other medicines also used in the treatment of migraine (ergotamine and ergotamine derivatives (including methysergide) or other triptans (5-hydroxytryptamine (5HT1) agonists).

Warnings and precautions

Talk to your doctor or pharmacist before taking Frovatriptan:
- if you are a patient at risk of coronary artery disease, including if:
  - you are a heavy smoker or a user of nicotine substitution therapy
  - you are a post-menopausal female or a male aged over 40 years
- Stop taking Frovatriptan and talk to your doctor right away:
  - if you experience a feeling of tightness or pain in the chest, shortness of breath and/or pain or discomfort in one or both arms, your back, shoulders, neck, jaw, or upper part of the stomach; these might be symptoms of a heart attack, which can occur when taking triptans, even in patients with no history of cardio-vascular disease (see also section 4);
  - if you have generalized skin rash and itching, rapid-onset swelling (especially around the lips, eyes, or of the tongue), with possible sudden difficulty in breathing and a fast heartbeat and thumping heart. These are all symptoms and signs of allergy and whole-body hypersensitivity reaction (see also section 4).

Children and adolescents

Do not give this medicine to children and adolescents (under 18 years of age) because the safety and efficacy of frovatriptan have not been established in these groups.

Other medicines and Frovatriptan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

You should not take this medicine at the same time as certain other medicines used for the treatment of migraine:
- especially ergotamine, ergotamine derivatives (including methysergide); you should allow at least 24 hours to elapse between the discontinuation of these medicines and the administration of Frovatriptan.
- Similarly, you should not take these medicines within 24 hours following a dose of Frovatriptan.
- especially other triptans (5-HT1 agonists, such as sumatriptan, almotriptan, eletriptan, naratriptan, rizatriptan or zolmitriptan).
- Unless otherwise directed by your doctor, you should not take this medicine at the same time as monoamine oxidase inhibitor (MAOI) medicines used in the treatment of depression (phenelzine, isocarboxazid, tranylcypromine, moclobemide).
- you should also tell your doctor or pharmacist if you are taking oral contraceptives or selective serotonin-reuptake inhibitors (citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline).

It is recommended that you do not take Frovatriptan at the same time as taking St. John's Wort (hypericum perforatum).

Concomitant use of Frovatriptan with the medicines listed above (especially monoamine oxidase inhibitors, selective serotonin-reuptake inhibitors and hypericum perforatum) may also increase the risk of serotonin syndrome (the symptoms of serotonin syndrome include: shivering, sweating, agitation, trembling and abrupt contraction of muscles, nausea, fever, confusion).

If you have any doubts about taking other medicines with and Frovatriptan, consult your doctor or pharmacist.

Frovatriptan with food and drink

Frovatriptan can be taken with food or on an empty stomach, always with plenty of water.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Frovatriptan should not be used during pregnancy or when breast feeding, unless you are told so by your doctor.
In any case, you should not breast-feed for 24 hours after taking the medicine and during this time any breast milk expressed should be discarded.

Driving and using machines

Frovatriptan and the migraine itself can cause drowsiness. If affected, driving or operating machinery can be dangerous and should be avoided.

Frovatriptan contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Frovatriptan contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3) How to take Frovatriptan

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take Frovatriptan as early as possible after the onset of the migraine headache.

Swallow one tablet whole with water.

If the first dose does not give you any relief, do not take a second dose during the same attack. You can use Frovatriptan for any following attacks. If you obtain relief after the first dose, but later on suffer from the re-appearance of a headache within 24 hours, you can take a second dose provided that at least 2 hours have elapsed between the 2 doses. Do not exceed the maximum dose of 5 mg (two tablets) in 24 hours.

Excessive use (repeated use over several consecutive days) of Frovatriptan constitutes incorrect use of this medicine and may cause an increase in side effects and lead to chronic daily headaches requiring the temporary discontinuation of treatment. Consult your doctor if you start having too frequent or daily headaches as you may be suffering from medication overuse headache.

Do not use this medicine to prevent migraines.

Use in children and adolescents

Frovatriptan should not be used in patients under 18 years of age.

Elderly

As there is little experience in patients over 65 years, the use of Frovatriptan is not recommended in patients in this age group.

If you take more Frovatriptan than you should

If you accidentally take an overdose of this medicine, tell your doctor or pharmacist immediately or go to the emergency department of your nearest hospital. Please remember to take the remaining tablets or this leaflet with you.

If you stop taking Frovatriptan

No special precautions are necessary when stopping the drugs.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
Like all medicines, this medicine can cause side effects, although not everybody gets them.

4) Possible side effects

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

Stop taking Frovatriptan and tell your doctor right away if you experience any of the following symptoms:

- a feeling of tightness or pain in the chest, shortness of breath and/or pain or discomfort in one or both arms, your back, shoulders, neck, jaw, or upper part of the stomach; these might be symptoms of a heart attack (myocardial infarction), which can occur when taking triptans, even in patients with no history of cardio-vascular disease;
- have generalized skin rash and itching, rapid-onset swelling (especially around the lips, eyes, or of the tongue and mucosa), with possible sudden difficulty in breathing and a fast heartbeat and thumping heart. These are all symptoms and signs of allergy and whole-body hypersensitivity reaction (hypersensitivity reactions, angioedema, anaphylaxis).

The side-effects reported with Frovatriptan were temporary, generally mild to moderate and disappeared spontaneously. Some symptoms reported may be caused by the migraine itself.

The following effects were **common (affecting more than 1 in 100 people and fewer than 1 in 10 people):**

- nausea (feeling sick, dry mouth, digestion problems, stomach pain,
- fatigue, chest discomfort (sensation of slight heaviness, pressure or tightness in the chest),
- headache, dizziness, sensation of pins and needles, most frequently in the arms and legs, reduction or disturbance of the sensations of touch, extreme sleepiness,
- hot flushes,
- tightness in the throat,
- sight disturbances,
- increased sweating.

The following effects were **uncommon (affecting more than 1 in 1,000 people and fewer than 1 in 100 people):**

- altered sense of taste, trembling, poor concentration, lethargy, increased sensation of touch, drowsiness, involuntary muscle contractions,
- diarrhoea, difficulty in swallowing, gas in stomach or bowel, stomach discomfort, bloated stomach,
- awareness of heart beat (palpitations), fast heartbeat, high blood pressure, chest pain (intense feeling of tightness or feeling of pressure in the chest),
- feeling hot, reduced tolerance of heat and cold, pain, weakness, thirst, sluggishness, increased energy, generally feeling unwell, sensation of spinning,
- anxiety, inability to sleep, confusion, nervousness, agitation, depression, loss of sense of personal identity, coldness in the hands and feet,
- irritation of the nose, inflamed sinus, sore throat and/or voice box,
- muscle stiffness, muscle and bone pain, pain in the hands and feet, back pain, painful joints,
- eye pain, eye irritation, painful oversensitivity to light,
- itchiness,
- ringing in the ears, earache,
- dehydration,
- passing urine frequently, production of large amounts of urine,

The following effects are **rare (affecting more than 1 in 10,000 people and less than 1 in 1,000 people):**

- muscle spasm, floppy muscles, diminution of reflexes (hyporeflexia), movement problems,
- constipation, burping, heartburn, irritable bowel syndrome, lip blisters, lip pain, spasm of the gullet, blisters in the mouth, ulcer in the stomach or upper part of the small intestine, pain in the salivary gland, inflammation of the mouth, toothache,
- fever,
- loss of memory, abnormal dreams, personality disorder,
- nosebleed, hiccups, overbreathing, breathing disorder, irritation in the throat,
- night blindness,
- skin reddening, sensation of hairs standing on end, purplish spots or patches on skin and mucous surfaces of the body, hives,
- slow heartbeat,
- ear discomfort, ear disorder, ear itchiness, sensitive hearing,
- increase in bilirubin (a substance produced by the liver) in the blood, decrease of calcium in the blood, abnormal urine analysis,
- low sugar in the blood,
- passing urine frequently at night, pain in the kidneys,
- self-inflicted injury (eg bite or bruising),
- swollen lymph nodes,
- breast pain or discomfort.

Although the frequency cannot be estimated from the available data, the following events were also reported:
- allergic reactions (hypersensitivity) including generalized skin rash and itching, rapid-onset swelling (especially around the lips, eyes, or of the tongue), with possible sudden difficulty in breathing, that can be associated with fast heartbeat and thumping heart (anaphylaxis),
- heart attack (myocardial infarction),
- chest discomfort or pain that is caused by a temporary spasm (constriction) in your coronary arteries (the blood vessels that bring oxygen and nutrients to your heart, i.e. coronary artery spasm).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Frovatriptan

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the blister and the outer carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Frovatriptan contains
The active substance is frovatriptan. Each tablet contains 2.5mg of frovatriptan (as frovatriptan succinate monohydrate).

The other ingredients are:
Tablet core: silicified microcrystalline cellulose, lactose anhydrous, silicon dioxide, sodium starch glycolate (Type A) and magnesium stearate.
Film-coating: hypromellose (E464), lactose monohydrate, macrogol 3350 (E1521), triacetin and titanium dioxide (E171).

What Frovatriptan looks like and contents of the pack
Frovatriptan are white to off white round film-coated tablets, plain on both sides.

They are available in blister packs of 6 tablets.

PL 46420/0009 Frovatriptan 2.5mg Film-coated Tablets **POM**

Who makes and repackages your medicine?
Your medicine is manufactured by Chanelle Medical, Loughrea, Co. Galway, Ireland or JSC Grindeks, 53 Krustpils street, Riga, LV-1057, Latvia. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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For any information about this medicine, or to request for a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Ltd on 020 8839 3000.