Package leaflet: Information for the patient

Frovatriptan 2.5 mg film-coated tablets

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

Frovatriptan contains the active ingredient frovatriptan which belongs to a group of medicines called triptans.

Frovatriptan is used to treat migraine headache in adults:

- Migraine symptoms may be caused by the widening of blood vessels in the head. Frovatriptan is thought to reduce the widening of these blood vessels. This helps to take away the headache and other symptoms of a migraine attack, such as feeling or being sick (nausea or vomiting) and being sensitive to light and sound.
- Frovatriptan works only when a migraine headache has started. You should not take Frovatriptan to prevent migraines occuring.

2. What you need to know before you take Frovatriptan

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 moderately high or very high blood pressure or mild high blood pressure that is not being treated.
- if you have or have had heart disease, a heart attack, angina (chest pain as a result of lack of oxygen in the heart muscle) or other signs of coronary heart disease such as breathlessness, extreme tiredness or ankle swelling.
- if you have peripheral vascular disease (narrowing of the vessels that carry blood to the legs and arms).
- if you have had a stroke or if you have had the symptoms of a stroke, which only lasted a short time and from which you made a complete recovery (transient ischaemic attack).
- if you are taking medicines containing ergotamine or medicines similar to ergotamine to treat migraine (including methysergide) or other triptans (see "Other medicines and Frovatriptan" for further information).
- if you have severe problems with your liver.

Warnings and precautions
Talk to your doctor or pharmacist before taking Frovatriptan if:
- you are at a higher risk of heart disease for example if you are a heavy smoker or you use nicotine replacement therapy. Your doctor should make additional checks especially if you are a woman after menopause or a man older than 40 years old.
- you have unusual forms of migraine caused by brain or eye problems.
- you are taking herbal medicines containing St John's wort (side effects may be more frequent).
- you are taking buprenorphine. The use of buprenorphine together with Frovatriptan can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Frovatriptan").

During treatment
If you get a serious allergic reaction when taking Frovatriptan such as flushing of the skin, nettle rash, swelling of the mouth, lips, tongue or throat causing difficulty breathing or swallowing, feeling sick (nausea) or being sick (vomiting), collapse or unconsciousness stop taking this medicine and contact your doctor or go immediately to the nearest hospital emergency department (see section 4 'Possible side effects').

When taking Frovatriptan, you may notice pain or a feeling of tightness in your chest and throat. If these symptoms do not pass quickly, stop taking frovatriptan and tell your doctor immediately.

If you have frequent or daily headaches while taking this medicine, stop taking Frovatriptan and contact your doctor. Using painkillers to treat headaches for longer than normal can make the headaches worse.

Children and adolescents
Frovatriptan should not be given to children and adolescents under the age of 18 as it is not known how this medicine may affect them.

Other medicines and Frovatriptan
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, inform your doctor if you are taking:
- Triptans other than frovatriptan (such as sumatriptan, almotriptan, eletriptan, naratriptan, rizatriptan or zolmitriptan). Do not take these medicines at the same time as Frovatriptan. After taking Frovatriptan, leave 24 hours before taking other triptans as this may result in high blood pressure, narrowing of the blood vessels of the heart or serotonin syndrome, a potentially life-threatening drug reaction (see section 4 'Possible side effects').
- Buprenorphine. Do not take this medicine at the same time as Frovatriptan as this may result in serotonin syndrome, a potentially life-threatening drug reaction.
- Ergotamine or medicines similar to ergotamine (used to treat migraines including methysergide and methylergometrine). Do not take these medicines at the same time as Frovatriptan as this may also result in high blood pressure, narrowing of the veins of the heart or serotonin syndrome. Wait at least 24 hours after taking Frovatriptan before taking these medicines or similarly, wait at least 24 hours after taking these medicines before taking Frovatriptan.
- Medicines for depression called selective serotonin re-uptake inhibitors (SSRIs) such as fluoxetine, citalopram, fluvoxamine, paroxetine or sertraline) as this may result in high blood pressure, narrowing of the blood vessels of the heart or serotonin syndrome.
- St John's wort (*Hypericum perforatum*), a herbal remedy used to treat depression, as this may result in serotonin syndrome.
- Medicines used to treat depression called monoamine oxidase inhibitors (MAOIs) such as moclobemide, phenelzine, isacarboxazid and tranylcypromine as these may cause high blood pressure or serotonin syndrome.
- Oral contraceptives as these may increase the amount of frovatriptan in your body.

The symptoms of serotonin syndrome may include a combination of the following: involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Pregnancy and breast-feeding
Pregnancy
Frovatriptan is not recommended in pregnant women and in women of childbearing age who do not use contraception unless clearly necessary as it is not known if it is safe to use.

Breast-feeding
Frovatriptan may be present in breast milk. Breast-feeding is not recommended unless necessary, in which case avoid breast-feeding for 24 hours after taking Frovatriptan.

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.

Driving and using machines
This medicine and the migraine itself may make you feel drowsy. Do not drive or operate machinery if you feel drowsy, are affected by a migraine attack or after taking Frovatriptan.

Frovatriptan contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Frovatriptan

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

The recommended dose is 2.5 mg to treat a migraine attack. Take this medicine as soon as possible after you start to get a headache. Do not take this medicine before you start to have a headache.

If the symptoms of migraine return within 24 hours, you may take a second dose of Frovatriptan. The second dose should not be taken within 2 hours of your first dose.

You should not take more than 2 doses of Frovatriptan a day. The maximum daily dose is 5 mg Frovatriptan in 24 hours.

The tablets should be swallowed whole and with water. You can take this medicine with or without food as it does not affect the way the medicine works.

Use in older patients (over 65 years)
The use of Frovatriptan is not recommended.

Patients with liver problems
Do not take Frovatriptan if you have serious liver problems (see section 2 'Do not take Frovatriptan').

If you take more Frovatriptan than you should
Contact your doctor or nearest hospital casualty department immediately. Take the container and any remaining tablets with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Contact your doctor immediately or go to your nearest hospital emergency department if you get the following:

Rare (may affect up to 1 in 1,000 people):
- Burning stomach pain, usually immediately or 1 to 2 hours after eating. This may be a sign of an ulcer in the stomach or upper part of the small intestine

Not known (frequency cannot be estimated from the available data):
- Serious allergic reactions such as flushing of the skin, nettle rash, swelling of the mouth, lips, tongue or throat causing difficulty breathing or swallowing, feeling sick (nausea) or being sick (vomiting), collapse or unconsciousness
- Sudden chest pain that may spread to the neck or arms with a clammy feeling or a shortness of breath. These may be signs of a heart attack (myocardial infarction)
- A pressing, tight or heavy sensation on your chest with chest pain that lasts for a short period of time. These may be signs of a temporary narrowing of the blood vessels of the heart (coronary artery spasm)

Other possible side effects include:

Common (may affect up to 1 in 10 people):
- Dizziness, headache, abnormal or lack of feeling when touching, tingling, pins and needles in the fingers or toes, sleepiness
- Warm sensation (flushing)
- Problems with your sight
- Increased sweating
- Stomach pain, feeling sick (nausea), indigestion, dry mouth
- Tiredness, chest discomfort, tightness in the throat

Uncommon (may affect up to 1 in 100 people):
- Change in sense of taste, trembling, poor concentration, lethargy, increased sensitivity to touching, twitching muscles
- Diarrhoea, difficulty in swallowing, wind, stomach upset, bloated stomach
- Fast heartbeat that feels like a thumping in your chest (palpitations), increased heart beat, chest pain
- Coldness in feet and hands
- Feeling hot, reduced tolerance of heat and cold, pain, weakness, thirst, sluggishness, increased energy, general feeling of being unwell
- Foggy head or feeling lightheaded, with a sensation of spinning when sitting or standing (vertigo)
- Anxiety, inability to sleep, confusion, nervousness, agitation, depression, loss of sense of personal identity
- Runny or stuffy nose, possibly with pain or tenderness in the face, sore throat
- Muscle or joint stiffness, muscle or joint pain, pain in the hands and feet, back pain
- Pain in the eye, eye irritation, painful oversensitivity to light
- Itchiness
- Ringing in the ears, earache
- Dehydration
- Passing abnormally large amounts of urine; urinating more frequently
- Increase in blood pressure

Rare (may affect up to 1 in 1,000 people):
- An increase or decrease in muscle tone, delay in reflexes, movement problems
- Constipation, belching, heartburn, irritable bowel syndrome, lip blisters, lip pain, spasm of the food pipe, blisters in the mouth, pain in the salivary gland, redness, irritation or swelling of the mouth, toothache
- Fever
- Loss of memory, abnormal dreams, changes to your personality
- Nosebleed, hiccups, very quick shallow breathing (hyperventilation), other breathing problems, sore 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 heart beat
- Ear discomfort, earache, ear itchiness, sensitive hearing
- Increase in bilirubin (a substance produced in the liver) in the blood or a decrease of calcium in the blood which can be seen in a blood test, abnormal urine test results
- Low sugar in the blood
- Passing urine frequently at night, pain in the kidneys
- Self-inflicted injury (bite)
- Swollen lymph nodes
- Breast tenderness

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

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.

6. Contents of the pack and other information

What Frovatriptan contains:
- Each film-coated tablet contains 2.5 mg of frovatriptan as frovatriptan succinate.
- The other ingredients are:
  * Tablet core: anhydrous lactose (see section 2 'Frovatriptan contains lactose and sodium'), microcrystalline cellulose, sodium starch glycolate (type A), magnesium stearate and colloidal anhydrous silica
  * Film-coating: hypromellose, titanium dioxide (E 171), macrogol 8000, macrogol 400.

What Frovatriptan looks like and contents of the pack

The tablets are white to off white, film-coated, round tablets with two sides that curve out marked with "M" on one side of the tablet and "FR" over "2.5" on the other side.

Frovatriptan is available in blister packs containing 2, 6 and 12 film-coated tablets and in perforated blister packs containing 2 x 1, 6 x 1 and 12 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan,
Potters Bar, Hertfordshire, EN6 1TL,
United Kingdom

Manufacturers

Mylan Hungary Kft,
H-2900 Komárom,
Mylan utca 1,
Hungary

This leaflet was last revised in May 2024.

Mylan

ART-52032-01
9158.2001

BACK