Sanomigran® 500 microgram Tablets and Sanomigran® 1.5 mg Tablets

Pizotifen (as malate)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

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1. What Sanomigran Tablets are and what they are used for

Sanomigran Tablets are available in two different strengths containing either 500 micrograms or 1.5 mg of the active ingredient, pizotifen.

Sanomigran Tablets are a migraine treatment. They may help to stop the effects of substances in your body called “serotonin”, “histamine” and “tryptamine” which are involved in causing some kinds of headache, including migraine.

Sanomigran Tablets have been prescribed for you by your doctor to help your migraine type headaches. If they are taken regularly they can help to prevent headaches or reduce the pain of cluster headaches, common and classical migraine. Sanomigran Tablets can stop some migraine attacks starting and help make some other attacks less severe. They will not stop migraine attacks once they have started.

2. Before you take Sanomigran Tablets

Do not take Sanomigran Tablets if:

- you are allergic (hypersensitive) to pizotifen or any of the other ingredients of Sanomigran Tablets listed in Section 6
- you are under 12 years of age.

Do not take Sanomigran Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Sanomigran Tablets.
Take special care with Sanomigran Tablets

Check with your doctor or pharmacist before taking your medicine if:

- you have glaucoma (raised pressure in your eyes)
- you ever have problems passing urine
- you have kidney problems, especially kidney failure (the medical term for this is renal failure)
- you have epilepsy
- you have any liver problems

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Sanomigran Tablets.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription or herbal medicines. This is because Sanomigran Tablets can affect the way some other medicines work.

Remind your doctor or pharmacist if you are taking:

- medicines called alpha- or beta- blockers (used to treat high blood pressure)
- medicines called monoamine oxidase inhibitors (used to treat depression)
- a medicine called Cisapride (used to treat heartburn)

Also some other medicines can affect the way Sanomigran Tablets work.

Anything that makes you sleepy may make you even sleepier if you are taking Sanomigran Tablets as well. This includes:

- sleeping pills or sedatives
- anti-histamines such as cold and hay fever medicines

Taking Sanomigran Tablets with food and alcohol

Do not drink alcohol when you are taking this medicine.

Pregnancy and breast-feeding

Talk to your doctor before taking Sanomigran Tablets if you are pregnant or might become pregnant. Do not breast-feed if you are taking Sanomigran Tablets.

Driving and using machines

Some people may feel drowsy or dizzy while they are taking Sanomigran Tablets. If this happens, you should not drive or do anything that requires you to be alert (such as operate tools or machines) until such problems clear.

Important information about some of the ingredients of Sanomigran

The tablets contain lactose and sucrose (types of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking Sanomigran.
3. How to take Sanomigran Tablets

Always take Sanomigran Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking Sanomigran Tablets

- With Sanomigran Tablets, you do not wait for a migraine and then treat the pain. You take it regularly to stop you migraines even beginning or to make them less severe.
- Swallow the tablets whole. Have a drink with them if this helps you to swallow.
- If you take your tablets once a day, take them in the evening a few hours before you go to bed as any drowsiness will help you to sleep.
- If you take your tablets in two or three doses, spread them evenly through the day.

How much to take

Adults

- You will start by taking one 500 microgram tablet each day. Your doctor will then slowly increase your dose.
- The usual dose is 1.5 mg of pizotifen each day. This is one 1.5 mg tablet or three 500 microgram tablets. You may have been told to take your tablets once a day or as three smaller doses.
- Do not take more than 3 mg in a single dose (two 1.5 mg tablets or six 500 microgram tablets). Do not take more than 4.5 mg (three 1.5 mg tablets or nine 500 microgram tablets) in a day.

Children (aged over 12 years)

- Children start by taking one 500 microgram tablet each day. The doctor will then slowly increase their dose.
- Children can take up to 1.5 mg of pizotifen each day. This is three 500 microgram tablets. This is usually best given in two or three smaller doses.
- Do not use the 1.5 mg tablets for children. Do not give them more than 1 mg in a single dose. This is two 500 microgram tablets.

If you forget to take Sanomigran Tablets

If you forget to take a dose of Sanomigran Tablets, do not worry. If you normally take Sanomigran Tablets several times a day you should take the last dose you missed as soon as you remember. Do not take it if there is less than 4 hours before your next dose, but go back to your regular dosing schedule. Do not take double doses or take more than your maximum daily dose.

If you normally take one tablet each day, take the next dose as soon as you remember. Take your next dose as usual. Do not take more than your maximum daily dose.

Tell your doctor if you keep forgetting to take your tablets.

If you take more Sanomigran Tablets than you should
All tablets can be risky if you take too many. If you take too many Sanomigran Tablets at once, tell your doctor or hospital casualty department as soon as possible. Take your medicine pack with you so that people can see what you have taken.

If you stop taking Sanomigran Tablets

Keep taking your tablets, even when you feel well. Your headaches may come back if you stop taking them. Talk to your doctor if you want to stop taking your tablets.

Do not stop taking them suddenly, or you may experience withdrawal symptoms, such as feeling anxious, shaking, insomnia, feeling sick, depression, dizziness, weight decrease and blackouts.

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

4. Possible side effects

Like all medicines, Sanomigran can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Tell your doctor straight away if you notice any of the following serious side effects:

- signs of allergy such as rash, itching or hives on the skin or swelling of the face
- you have seizures (fits)
- yellowing of your skin or the whites of your eyes, abnormal darkening of the urine or unexplained nausea, vomiting and tiredness (signs of jaundice or hepatitis).

Tell your doctor straight away if you notice any of the above.

Other side effects:

Very common (more than 1 in 10 people have experienced):

Increase in appetite and weight gain. An increase in appetite may lead to an increase in bodyweight. If you feel hungrier than usual, try to fill up on fresh low calorie foods. These are much healthier than processed high calorie foods. Your doctor can give you advice about diet as some kinds of foods are known to trigger migraine.

Common (up to 1 in 10 people have experienced):

Drowsiness, tiredness, dizziness, dry mouth, nausea.

Uncommon (up to 1 in 100 people have experienced):

Constipation.

Rare (up to 1 in 1000 people have experienced):

Depression, excitability or restlessness, hallucinations (seeing, hearing or feeling things that are not there), insomnia, anxiety, tingling or numbness of the hands or feet, muscle pain.

Unknown

Muscle cramps.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Sanomigran Tablets
   - Keep out of the reach and sight of children.
   - Do not use after the expiry date printed on the packaging. The expiry date refers to the last day of that month.
   - Keep the blister strips in the outer carton in order to protect from light. Only remove them when it is time to take your medicine.
   - Medicines should not be disposed of via wastewater or household waste. As your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Sanomigran Tablets contain
   - The active substance is pizotifen (present as pizotifen hydrogen malate). There are two strengths of Sanomigran Tablets; 500 micrograms and 1.5 mg.

   Sanomigran 500 microgram tablets contain 0.5 mg of the active substance pizotifen (as 0.725 mg of pizotifen hydrogen malate).

   Sanomigran 1.5 mg tablets contain 1.5 mg of the active substance pizotifen (as 2.175 mg of pizotifen hydrogen malate).

   - The other ingredients are:
     - tablet core – lactose monohydrate, maize starch, povidone, magnesium stearate, talc
     - tablet coating – acacia gum, talc, sucrose, colloidal anhydrous silica, carnauba wax, printing ink and colouring agents, titanium dioxide (E171) and yellow iron oxide (E172).

What Sanomigran Tablets look like and contents of the pack

   - Sanomigran 500 microgram tablets are small ivory to yellow tablets marked SMG on one face. They come in packs of 60 tablets.
   - Sanomigran 1.5 mg tablets are large ivory to yellow tablets marked SMG 1.5 on one face. They come in packs of 28 tablets.

Marketing Authorisation Holder

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