

PACKAGE LEAFLET – INFORMATION FOR THE USER

PARAMAX 500mg/5mg Effervescent Powder Paracetamol Metoclopramide hydrochloride

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 onto 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

What is in this leaflet:

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

1. WHAT PARAMAX IS AND WHAT IT IS USED FOR

The name of your medicine is Paramax 500mg/5mg Effervescent Powder (called Paramax in this leaflet).

What Paramax contains

Paramax contains two different medicines. These are called:

- **Metoclopramide hydrochloride:** this belongs to a group of medicines called anti-emetics. It works on muscles in the upper part of the digestive system causing your stomach to empty. It also works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting)
- **Paracetamol:** This belongs to a group of medicines called painkillers (analgesics). It works by stopping substances that naturally occur in your body called prostaglandins from being made. Prostaglandins cause pain. If they are blocked, pain is relieved

What Paramax is used for

Paramax is used to the signs of migraine, such as headache, feeling sick (nausea) or being sick (vomiting) in adults 18 years and over.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARAMAX

Do not take this medicine and tell your doctor if:

- You are allergic to the active substances or any of the other ingredients (listed in section 6) Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have a blockage or bleeding in your stomach or intestine (gut)
- You have had movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs after taking metoclopramide or medicines used to calm emotional and mental problems
- You have epilepsy
- You have had an operation on your stomach or intestine (gut). Do not take during the first 3 to 4 days after your operation
- You have a tumour on the adrenal gland (called pheochromocytoma)
- You are taking a medicine called levodopa used to treat Parkinson's disease (see 'Other medicines and Paramax')

Children

Paramax must not be given to patients under 18 years of age. Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Paramax

Warnings and precautions

Take special care with Paramax

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

- You have severe kidney problems
- You have severe liver problems including alcoholic liver disease
- You are elderly (65 years of age or older)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Paramax

Other medicines and Paramax

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Paramax can affect the way some other medicines work. Also, some other medicines can affect the way Paramax works. These medicines include the following:

- Cholestyramine - for lowering blood cholesterol levels

While taking Paramax you should not take any other medicines which contain paracetamol.

This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Do not take this medicine, and tell your doctor, if you are taking:

- Levodopa – used for Parkinson's disease

Tell your doctor if you are taking any of the following:

Paramax may increase the effects of the following medicines:

- Medicines for mental illness known as 'antipsychotics'

- Medicines to calm or reduce anxiety (hypnotics, anxiolytics)
- Medicines to help you sleep (sedatives, barbiturates)
- Some medicines used for depression such as mirtazapine or trazodone
- Chloramphenicol – an antibiotic used for infections
- Medicines to prevent blood clotting (anti-coagulants) such as warfarin
- Ciclosporin – used to help prevent rejection of transplants. Your doctor may change your dose of ciclosporin
- Clonidine – used for high blood pressure, migraine or hot flushes in the menopause
- Some medicines for moderate to severe pain (morphine products) such as codeine, dihydrocodeine or dextropropoxyphene
- Medicines that can make you sleepy that are used for hay fever, rashes or other allergies called sedative antihistamines such as chlorphenamine or promethazine

Paramax can make the following medicine work less well:

- Digoxin – used for heart problems. Your doctor may change your dose of digoxin

The following medicine can increase the effects of Paramax:

- Domperidone (a similar medicine to metoclopramide) – used to stop you feeling sick (nausea) or being sick (vomiting)

The following medicines can make Paramax work less well:

- Oral contraceptive pill
- Colestyramine – for lowering blood cholesterol levels
- Medicines used to treat muscle spasms (anticholinergics) for irritable bowel syndrome (IBS) such as mebeverine or hyoscine
- Medicines used to treat incontinence such as oxybutynin, propiverine or tolterodine
- Some medicines for moderate to severe pain (morphine products) such as codeine, dihydrocodeine or dextropropoxyphene

Paramax with alcohol

You should not drink alcohol while you are taking these sachets. Drinking alcohol while taking Paramax may make you feel very sleepy.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if:

- You are pregnant, think you may be pregnant or plan to get pregnant. You must not take Paramax during the first six months of pregnancy.
- You are breast-feeding or planning to breast feed. Do not breast-feed if you are taking Paramax. This is because small amounts may pass into mothers' milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel sleepy after taking this medicine. This is more likely if you have drunk alcohol or taken other medicines that cause drowsiness. If this happens, do not drive or use any tools or machines.

Paramax contains:

Sodium:

There is 387.7 mg of sodium per sachet. This may be harmful to people on a low sodium or low salt diet.

3. HOW TO TAKE PARAMAX

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

Taking this medicine

- Take this medicine by mouth
- Pour the contents of the sachet into about a quarter of a glass of water mix well and drink straight away
- Do not take more than the recommended dose
- If you continue being sick (vomiting) after taking this medicine, tell your doctor
- If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor

How much to take

Adults (18 years and older) and the elderly:

- The usual dose is 2 sachets when you have the first warning of a migraine attack
- Wait at least 4 hours before taking another dose
- Do not take more than 6 sachets in any 24 hour period

Use in children and adults under 18

Do not take if you are under 18 years of age.

If you take more Paramax than you should

- Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.
- Remember to take any remaining sachets and the pack with you. This is so the doctor knows what you have taken

The following effects may happen:

- Feeling sick (nausea) and being sick (vomiting); unusually pale complexion; loss of appetite; stomach pains. Other effects such as drowsiness, rapid uncontrollable shaking (convulsion), muscle spasms and 'jerks' may also occur
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis
- You may also feel that your limbs are swollen (fluid retention). This is a sign of changes in the way your kidneys are working

- In some cases an uneven heart beat; increased or heavy breathing and feeling weak. You may also develop liver problems that may cause the eyes or skin to go yellow and in severe cases lack of awareness (disorientation), confusion, bleeding in your stomach or gut, loss of consciousness (coma) and death may occur

If you forget to take Paramax

If you forget to take a dose at the right time, take it as soon as you remember. However do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

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.

Stop taking Paramax and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. Severe allergic reactions can occur (frequency is not known) and usually happen soon after taking Paramax. These can involve difficulty breathing, tightness in the throat, rapidly spreading rashes, dizziness, very fast heart beat or even loss of consciousness.
- You are short of breath, have bluish skin colouration, headache, tiredness, dizziness and loss of consciousness. These could be signs of a very rare but serious side effect called methaemoglobinaemia
- You have very high blood pressure (hypertension), symptoms of which may include a dull headache, dizziness, confusion, fatigue
- You are paler than normal, are sweating, have a high temperature, fast heartbeat, stiff muscles, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious side effect called neuroleptic malignant syndrome.
- Shortness of breath, slow heart beat and chest pain
- You have a fit (seizure)
- You get serious skin reactions. Very rare cases have been reported.
- You get infections or bruise more easily than usual. This could be because of a blood problem. (very rare may affect up to 1 in 10,000 people)
- Feeling tired, faint, dizzy and having pale skin. These could be signs of anaemia from an underlying Glucose-6-phosphate-dehydrogenase deficiency. (frequency not known)
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage. (frequency not known)

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

- Problems controlling certain muscles of the body or you have muscle spasms or 'jerks'. The affected muscles may include your tongue, mouth, jaw, arms and legs. The spasms may cause unusual movements of the face, tongue, eyes, neck and affect speech, expression and/or lead to unnatural positioning of the head and shoulders
- Decreased level of consciousness, confusion, hallucination

- Rigid or stiff muscles, trembling or shaking or difficulty moving
- You bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- You get infections more often and easier than normal. This could be because you have a low number of white blood cells (agranulocytosis)
- Depression

Tell your doctor as soon as possible if you have any of the following side effects:

- Diarrhoea
- Dizziness, lightheadedness and fainting. This could be because of low blood pressure

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Abnormal production of breast milk in men and women
- Breast enlargement in men
- Loss of menstrual periods
- Feeling nervous (anxious), restless or confused
- Feeling drowsy
- Lack or loss of strength (weakness)
- Skin rash

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 PARAMAX

Keep this medicine out of the sight and reach of children.

Do not use Paramax after the expiry date which is stated on the sachet and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Keep the sachets in the outer carton.

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 Paramax contains

- The active substances are metoclopramide hydrochloride and paracetamol. Each sachet contains 500mg paracetamol and 5mg metoclopramide hydrochloride (as anhydrous) as the active ingredients.
- The other ingredients are gelatin, sodium carbonate, saccharin sodium, sodium dihydrogen citrate (anhydrous), sodium bicarbonate and lemon flavour.

What Paramax looks like and contents of the pack

A white, soluble effervescent powder for oral solution.

Cartons containing 6, 30 or 42 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and ManufacturerMarketing Authorisation Holder

Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

Manufacturer

Sanofi-Aventis Sp. z o.o., ul. Lubelska 52, 35-233

Rzeszów, Poland

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