1. WHAT PROCHLORPERAZINE IS AND WHAT IT IS USED FOR

The name of your medicine is Prochlorperazine Maleate 5mg Tablets (called prochlorperazine in this leaflet). It belongs to a group of medicines called ‘phenothiazine antipsychotics’.

It works by blocking the effects of a chemical in the brain.

Prochlorperazine can be used to:
- Treat balance problems or dizziness (vertigo). This includes problems of the inner ear such as ‘Meniere’s Syndrome’ or ‘labyrinthitis’.
- Stop you feeling sick (nausea) or being sick (vomiting). This can be from any cause including migraines.
- Treat schizophrenia.
- Treat over-active behaviour or thoughts (mania).
- Treat anxiety in the short-term, when used in addition to other medicines.

2. BEFORE YOU TAKE PROCHLORPERAZINE

Do not take this medicine and tell your doctor if:
- You are allergic (hypersensitive) to prochlorperazine maleate or any of the other ingredients of prochlorperazine (listed in Section 6).
- You have ever had a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.

Take special care and check with your doctor or pharmacist before taking prochlorperazine if:
- You are elderly (65 years of age or older).
- You have an unusually pale complexion, feel confused, drowsy or agitated. These symptoms may mean you have problems when passing water (urine).
- You or someone else in your family has a history of blood clots. Some medicines like these have been associated with formation of blood clots.
- You have Parkinson’s disease.
- You have dementia.
- You have epilepsy or you have ever had fits (seizures).
- You have depression.
- You have a tumour on your adrenal gland called ‘phaechromocytoma’.
- You have a type of muscle weakness called ‘myasthenia gravis’.
- You have or you have ever had glaucoma (signs include painful eyes with blurred vision).
- You have or you have ever had a low number of white blood cells (agranulocytosis). This would lead you to get infections more easily than usual.
- You have low blood levels of potassium, calcium and magnesium. Your doctor may perform blood tests to check on these.
- You are not eating properly or are very under-weight.
- You have a history of alcohol problems.
- You are elderly (65 years of age or older).
- The person is a child. This is because children may develop unusual face and body movements (dystonic reactions).

3. HOW TO TAKE PROCHLORPERAZINE

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

Taking this medicine:
- Take this medicine by mouth.
- Do not give to children under 1 year of age or who weigh less than 10 kg.
- You should not let the tablets touch your skin for very long, as you may get skin redness, swelling and itching (contact skin sensitisation).
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

4. POSSIBLE SIDE EFFECTS

In this leaflet:
- • Breathing problems
- • Convulsions (fits)
- • Difficulty in swallowing
- • Dizziness
- • Dry mouth
- • Feeling restless or agitated
- • Breast enlargement in men
- • Abnormal production of breast milk in men
- • Feeling or being sick or difficulty sleeping.
- • After several weeks of treatment, your doctor may have given you this medicine.
- • Your doctor may have given you this medicine before another company. It may have looked slightly different. However, either brand will have the same effect.

Prochlorperazine Maleate 5mg Tablets
Prochlorperazine maleate

REPORTING OF SIDE EFFECTS

By reporting side effects you can help provide more information on the safety of this medicine.

If you have any further questions about your medicine, talk to your doctor or pharmacist.

Driving and using machines

You may feel sleepy after taking this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of prochlorperazine:
- Lactose: This medicine contains lactose, a type of sugar. If you are allergic to milk, you should not use this medicine.

Pregnancy and breast-feeding

Do not take prochlorperazine if:
- You are pregnant, might become pregnant or think you might be pregnant.
- You are breast-feeding or planning to breast-feed.

The following symptoms may occur in newborn babies of mothers that have used prochlorperazine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

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

Adults:
- Treatment of balance problems or dizziness (vertigo):
  - The usual dose is 5 mg three times each day
  - This may be increased to a total daily dose of 30 mg each day
  - After several weeks treatment, your doctor may decide to gradually lower your daily dose to 5 to 10 mg each day

Stopping you feeling sick or being sick:
- The usual dose is 5 or 10 mg
- This may be taken two or three times each day

Treatment of feeling sick or being sick:
- To begin with you will usually take 20 mg
- This may be followed by 10 mg two hours later

Treat over-active behaviour or thoughts (antipsychotics):
- This is a group of medicines called ‘phenothiazene’ and the name of your medicine is prochlorperazine. It belongs to a group of medicines known as ‘antipsychotics’.

1. WHAT PROCHLORPERAZINE IS AND WHY YOU ARE TAKING IT

You have been prescribed prochlorperazine to help treat one of the following:
- Short-term treatment of anxiety:
  - A dose of 0.25 mg for each kilogram of your child’s weight. A dose of 0.5 mg may be given two or three times a day.
  - The starting dose will be 15 to 20 mg twice each day for seven days.
  - Your doctor may increase your dose up to a total daily dose of 75 to 100 mg each day.
  - After several weeks of treatment, your doctor may then lower your dose to a total daily dose of 25 to 50 mg each day.

- Short-term treatment of anxiety:
  - The starting dose will be 15 to 20 mg each day in divided doses.
  - Your doctor may then increase your dose to a total daily dose of 40 mg each day.

- Elderly:
  - Your doctor may prescribe a lower dose.
  - You should be careful during very hot or very cold weather to make sure that you do not get too hot or too cold.

- Children (over 1 year of age and weighing more than 10 kg):
  - Stopping your child feeling sick or being sick:
    - Your doctor will decide the dose according to your child’s weight.
    - A dose of 0.25 mg for each kilogram of your child’s weight is usually given.
    - This dose may be given two or three times a day.
  - If you take more prochlorperazine than you should:
    - If you take more prochlorperazine than you should, seek a doctor or go to a hospital.
    - Take the medicine pack with you. This is so the doctor knows what you have taken. Taking too much prochlorperazine may cause symptoms such as feeling sleepy or dizzy, increased or rapid heartbeat, feeling very cold and confused, withings movements, feeling restless, stiffness or shaking. You may lose consciousness.
    - You may forget to take prochlorperazine:
      - If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

- If you stop taking prochlorperazine:
  - Keep taking prochlorperazine until your doctor tells you to stop. Do not stop taking prochlorperazine just because you feel better.
  - Your doctor will gradually stop your medicine to prevent these effects happening.

Exposure to sunlight:
Prochlorperazine can cause your skin to be more sensitive to sunlight. You should avoid exposure to direct sunlight while taking this medicine.

Tests:
Your doctor may do regular tests while you are taking this medicine. These might include blood tests and an ECG to check your heart is working properly.

If you have any further questions about taking prochlorperazine ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop taking prochlorperazine and see a doctor or go to a hospital straight away if:
- You have an allergic reaction. The signs may include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.
- You have an unusually pale complexion, sweating, 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’.
- You have frequent infections such as fever, sore throat or mouth ulcers. These could be signs of a blood problem called leucopenia.
- You may get infections more easily than usual. This could be because of a blood disorder (agranulocytosis).
- You have yellowing of your skin or eyes (jaundice). These could be signs of liver problems.
- You have a very fast, uneven or forceful heartbeats (palpitations) and experience breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain.
- You have blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- You have rigid or stiff muscles, trembling or shaking, unusual eye movements (including rolling of the eyes), difficulty moving, or loss of muscle control.

Tell your doctor as soon as possible if you have any of the following side effects:
- Breathing problems.
- Changes in your skin or eye colour after taking prochlorperazine for a long period of time.
- Problems with your eyesight after taking prochlorperazine for a long period of time.
- Feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure).
- Passing large amounts of urine, excessive thirst and having a dry mouth or skin.
- You may also be more likely to get infections, such as thrush. This could be due to too much sugar in your blood (hyperglycaemia).

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.
- Difficulty in getting or maintaining an erection (impotence).
- Difficulty sleeping (insomnia).
- Feeling restless or agitated.
- Dry mouth.
- Your skin being more sensitive to the sun than usual.
- Stuffy nose.
- Skin redness, swelling and itching from touching the medicine.

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PROCHLORPERAZINE

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use prochlorperazine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store protected from light.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What prochlorperazine contains
- Each tablet contains 5 mg of the active substance, prochlorperazine maleate.
- The other ingredients are lactose, maize starch, aerosil (E551) and magnesium stearate.

What prochlorperazine look like and contents of the pack
Prochlorperazine Tablets are off-white to pale cream coloured circular tablets. The tablets marked “4L1” on one side.

Prochlorperazine Tablets are available in blister packs containing 28 or 84 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Sanofi, One Onslow Street, Guildford, GU1 4YS, UK.
Manufacturer

This leaflet was last revised in June 2013