PACKAGE LEAFLET: INFORMATION FOR THE USER

Dolmatil® 200mg Tablets
sulpiride

Is this leaflet hard to see or read? Phone +353 1 428 7777 for help
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 pharmacist

In this leaflet:
1. What Dolmatil Tablets are and what they are used for
2. Before you take Dolmatil Tablets
3. How to take Dolmatil Tablets
4. Possible side effects
5. How to store Dolmatil Tablets
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1. What Dolmatil Tablets are and what they are used for
Dolmatil Tablets contains a medicine called sulpiride. This belongs to a group of medicines called 'benzamides'. It works by blocking the effect of a chemical in the brain. Dolmatil Tablets are used to treat Schizophrenia.

2. Before you take Dolmatil Tablets
Do not take this medicine and tell your doctor if:
X You are allergic (hypersensitive) to sulpiride or any of the other ingredients of Dolmatil Tablets (listed in Section 6 Further Information) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
X You have a tumour on the adrenal gland called 'phaechromocytoma'
X You have a rare illness called 'porphyria' which affects your metabolism
X You have breast cancer or cancer in the pituitary gland
X You are taking levodopa or ropinirole used for Parkinson's disease (see 'Taking other medicines' below) 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 Dolmatil Tablets.

Take special care with Dolmatil Tablets
Check with your doctor or pharmacist before you take this medicine if:
. You have bouts of aggressive behaviour or are very agitated
. You have kidney problems
. You have heart problems or a family history of heart problems. Your doctor may test your heart function before you take this medicine
. You have ever had a stroke
. You have low levels of potassium in your body (hypokalaemia)

. If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
. The person is 65 years of age or older
. You have dementia
. You have Parkinson's disease
. You have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
. You have epilepsy or have had fits (seizures)
. You have high blood pressure
. You have a history of glaucoma
. You or your family have a history of stomach problems
. You or your family have a history of breast cancer
If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Dolmatil Tablets.

Medicines of this type (antipsychotics) can cause a combination of fever, muscle rigidity and vegetative symptoms, such as sweating or faster breathing (called "neuroleptic malignant syndrome"). If this happens, treatment must be stopped and you should talk to a doctor immediately.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Dolmatil Tablets can affect the way some other medicines work. Also some medicines can affect the way Dolmatil works.

In particular, do not take this medicine and tell your doctor if you are taking:
• Levodopa or ropinirole used for Parkinson's disease

Tell your doctor if you are taking any of the following medicines;
• Medicines to control your heartbeat such as amiodarone, sotalol, disopyramide or quinidine
• Medicines for high blood pressure or heart disorders, such as clonidine, diltiazem, verapamil or digitalis
• Other medicines for schizophrenia such as pimozide, haloperidol, thioridazine
• Lithium used for some types of mental illness
• Some medicines to help you sleep or lower your anxiety
• Other medicines used to calm emotional and mental problems
• Water tablets (diuretics) that can lower the levels of potassium in your blood
• Some medicines used for constipation (laxatives) that can lower the levels of potassium in your blood
• Some medicines used for infections (antibiotics) such as pentamidine, erythromycin or amphotericin B
• Tetracosactide used to test the function of your adrenal gland
• Steroids used to lower inflammation such as prednisolone, betamethasone, dexamethasone
• Some medicines for depression such as imipramine
• Medicines for indigestion and heartburn
• Sucralfate used for stomach ulcers
• Medicines for pain relief. These may also be included in medicines for colds and flu
• Some medicines used for allergies (anti-histamines that make you sleepy) such as chlorphenamine, promethazine, ketotifen

• Ropinorole used for Parkinson's disease
• Methadone used for pain relief and as a drug substitute
• Halofantrine used for malaria

Taking Dolmatil Tablets with food and drink
Do not drink alcohol or take medicines that contain alcohol while being treated with Dolmatil Tablets. This is because alcohol can increase the effects of Dolmatil Tablets.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy:
Dolmatil is not recommended during pregnancy and in women of child-bearing potential not using effective contraception.
If you use Dolmatil during the last three months of pregnancy, your baby may suffer from agitation, increased muscle tension, involuntary trembling of the body, somnolence, respiratory distress or feeding disorder. Talk to your doctor if your baby develops any of these symptoms.

Breastfeeding:
You should not breast-feed during therapy with Dolmatil. Talk to your doctor about the best way to feed your baby if you are taking Dolmatil.

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 Dolmatil Tablets
• Lactose. Dolmatil Tablets contain lactose. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Dolmatil tablets

3. How to take Dolmatil Tablets

Always take Dolmatil Tablets 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
• Swallow the tablets whole with a drink of water
• 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
• The usual starting dose is 400mg (two 200mg tablets) to 800mg (four 200mg tablets) daily depending on your illness.

• Your doctor may then change your dose depending on your illness

Patients with Kidney Disease
• The starting dose may be lower and the rate of increasing the dose slower.

Children under 14 years of age
Dolmatil Tablets are not recommended for children under 14 years of age.

If you take more Dolmatil Tablets than you should
If you take more Dolmatil Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling restless, confused or agitated, having a reduced level of consciousness, trembling, muscle stiffness or spasm, difficulty in movement, movements that you cannot control (for example of the eyes, neck, arms and legs), producing more saliva than usual. In some cases dizziness, light-headedness, fainting (due to low blood pressure) and coma have happened. Fatal outcomes have been reported in combination with other medicines which affect the brain.

If you forget to take Dolmatil Tablets
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.

If you stop taking Dolmatil Tablets
Keep taking Dolmatil Tablets until your doctor tells you to stop. Do not stop taking Dolmatil Tablets just because you feel better. If you stop taking Dolmatil Tablets suddenly, your illness may come back and you may have other unwanted effects such as feeling or being sick, sweating and difficulty sleeping. In some cases you may also feel restless or have movements that you cannot control (for example of the eyes, neck, arms and legs).
Your doctor will gradually lower your dose until you stop your medicine, to prevent these effects happening.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Dolmatil Tablets can cause side effects, although not everybody gets them.
If you experience any of the below you should stop taking Dolmatil tablets and visit your doctor or go to a hospital immediately

• You have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling
• You have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs
• You have fits
• 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. If left untreated, it is possible that it could lead to a blockage of the main artery of the lung (pulmonary embolism). Symptoms of this include very fast or very slow, uneven forceful heart-beats. You may also have problems breathing such as wheezing, shortness of breath, tightness and or pain in your chest.

• In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking anti-psychotics compared with those not receiving antipsychotics.
• You have a high temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious but rare side effect called 'neuroleptic malignant syndrome'
• Abnormal fast heartbeat, life threatening irregular heartbeat including cardiac arrest, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart)
• You get more infections than usual. This could be because of a blood disorder (agranulocytosis) or a decrease in the number of white blood cells (neutropenia)
• You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
• You have unexplained sore throat or swelling in the neck, armpit and/or groin.
Not known (frequency cannot be estimated from the available data):

- Muscle breakdown resulting in kidney damage (rhabdomyolysis)
- Increased level of creatine phosphokinase in blood (an indicator of muscle damage)
- Fever

Tell a pharmacist or doctor as soon as possible if you have any of the following side effects:
Common (may affect up to 1 in 10 people)
• Feeling restless and not being able to keep still (akathisia)
Uncommon (may affect up to 1 in 100 people)
• Feeling dizzy, light-headed or faint when you stand or sit up quickly (due to low blood pressure)
• Producing more saliva than usual
Rare (may affect up to 1 in 1,000 people)
• Rolling of the eyes
Not known (frequency cannot be estimated from the available data)
• Rigid or still muscles, trembling or shaking, difficulty moving
• Your neck becomes twisted to one side
• Your jaw is tight and stiff
• Increase in blood pressure
• You feel confused
• Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH)
• Blood tests showing less sodium than usual in your blood
• Problems with your liver, which will show up on blood tests
• You develop a lung infection after inhaling food, liquid, saliva or nasal secretions (pneumonia aspiration)

Talk to your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:
Common (May affect up to 1 in 10 people)
• Abnormal production of breast milk in men and women
• Weight gain
• Painful breasts in men and women
• Feeling drowsy or sleepy
• Difficulty sleeping (insomnia)
• Skin rashes
• Constipation

Uncommon (may affect up to 1 in 100 people)
• Breast enlargement in men and women
• Loss of menstrual periods
• Difficulty in getting or keeping an erection or in ejaculating (impotence) or being unable to have an orgasm
• There have been very rare reports of sudden death with Dolmatil. These are possibly caused by heart problems.

Blood tests
Dolmatil Tablets can increase the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dolmatil Tablets
Keep this medicine in a safe place where children cannot see or reach it. Do not use Dolmatil Tablets after the expiry date which is stated on the label and carton.
The expiry date refers to the last day of that month.
There are no special storage conditions.

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 Dolmatil Tablets contains
• Each tablet contains 200mg of the active substance sulpiride
• Other ingredients include: potato starch, lactose monohydrate, methylcellulose, talc, magnesium stearate and colloidal hydrated silica.

What Dolmatil Tablets looks like and contents of the pack
• Dolmatil® 200mg Tablets are white to ivory white round tablets, cross scored on one side and engraved on the other side "SPD200". Supplied in blisters packs of 100 (10X10) tablets.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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