

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 questions or are unsure of anything, ask your doctor or pharmacist for more information.
- . This medicine has been prescribed for you personally and you should 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this package leaflet:

1. What Dogmatil 200 mg scored tablets are and what they are used for
2. Before you take Dogmatil 200 mg scored tablets
3. How to take Dogmatil 200 mg scored tablets
4. Possible side effects
5. How to store Dogmatil 200 mg scored tablets
6. Further Information

1. WHAT Dogmatil 200 mg scored tablets ARE AND WHAT THEY ARE USED FOR

NEUROLEPTIC ANTIPSYCHOTIC
BENZAMIDE

This medicine is used to treat certain behavioral disorders in adults.

2. BEFORE YOU TAKE Dogmatil 200 mg scored tablets

If your doctor has told you that you are intolerant to certain sugars, please contact him/her before taking this medicine.

Never take Dogmatil 200 mg scored tablets in the following cases:

- hypersensitivity to sulpiride or to one of the other ingredients of the product,
- diagnosed prolactin-dependent tumor, e.g. pituitary gland tumor or breast cancer,
- pheochromocytoma (a condition affecting the adrenal medulla, causing severe high blood pressure),
- in combination with dopamine agonists not for use as antiparkinsonian agents: cabergoline and quinagolide (drugs used for lactation disorders) (see "Taking other medicines").

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with Dogmatil 200 mg scored tablets

Special warnings

In the event of unexplained fever, paleness or heavy sweating, it is essential that you alert a doctor or an emergency medical service immediately.

In order to detect any potential heart disorders, your doctor may ask you to undergo an electrocardiogram. This is because this medicine can cause heart rhythm disorders (see Section 4. POSSIBLE SIDE EFFECTS).

This medicine should be used with caution in patients who have risk factors for stroke.

This medicine should be used with caution in elderly patients suffering from dementia.

This medicine should be used with caution if you or a family member have a history of blood clots since taking antipsychotic drugs has been associated with the formation of blood clots.

It is inadvisable to use this drug with drinks or medicines containing alcohol, with levodopa, dopamine antiparkinsonian drugs, antiparasitics likely to induce torsades de pointes (serious heart rhythm disorders), methadone, other neuroleptics and drugs likely to induce torsades de pointes (see "Taking other medicines").

This medicine contains lactose. You should not use this medicine if you have galactose intolerance, Lapp lactase deficiency or glucose and galactose malabsorption syndrome (rare hereditary diseases).

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Precautions for use

You must inform your doctor if you have any of the following so that he/she can adjust the dosage and/or treatment monitoring:

- heart disease,
- Parkinson's disease,
- kidney failure,
- a history of seizures (long standing or recent), or epilepsy.
- diabetes or risk factors for diabetes.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking other medicines

This medicine **must not be taken** with cabergoline or quinagolide (medicines used for lactation disorders) (See "Never take Dogmatil 200 mg scored tablets in the following cases).

Using this medicine with the following substances **must be avoided**:

- certain medicines for the treatment of Parkinson's disease,
- certain medicines that can induce torsades de pointes (serious heart rhythm disorders),
- drinks or medicines containing alcohol.

PLEASE INFORM YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING OR HAVE RECENTLY TAKEN ANY OTHER MEDICINES, INCLUDING THOSE OBTAINED WITHOUT A PRESCRIPTION.

Pregnancy

This medicine should only be used during pregnancy on the advice of your doctor.

If you discover that you are pregnant, consult your doctor so that he/she can determine whether it is necessary to continue treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Breast-feeding is not recommended during treatment with this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You should be aware, especially if you drive or use machines, that this medicine may cause drowsiness.

Important information about certain ingredients of Dogmatil 200 mg scored tablets

Lactose.

3. HOW TO TAKE Dogmatil 200 mg scored tablets

How many Dogmatil 200 mg scored tablets should be taken For use in adults only.

The dosage is variable and must be adapted to each individual case.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

How Dogmatil 200 mg scored tablets are taken

Oral use.

How long Dogmatil 200 mg scored tablets are taken

FOLLOW YOUR DOCTOR'S PRESCRIPTION.

If you take more Dogmatil 200 mg scored tablets than you should

If you take too high a dose of the medicine, immediately alert a doctor or an emergency medical service because of the risk of serious heart disorders.

4. POSSIBLE SIDE EFFECTS

As with all medicines, Dogmatil 200 mg scored tablets can cause side effects although not all patients have them.

- absence of menstrual period, enlarged breasts, abnormal secretion of milk from the nipple,
- impotence, frigidity,
- weight gain,
- drowsiness,
- shaking, rigidity and/or abnormal movements including facial (and tongue) movements,
- dizziness on standing from a lying or sitting position,
- heart rhythm disorders, which may lead to death (see Section "Special Warnings")
- seizures,
- rash,
- increase in liver enzymes.
- venous blood clots, particularly in the legs (symptoms include swelling, pain and redness in the legs) may pass through the blood vessels to reach the lungs, causing chest pain and difficulty breathing. If you experience any of these symptoms, see a doctor immediately.
- neuroleptic malignant syndrome which can be life-threatening: unexplained fever, sweating, paleness, change in blood pressure or heart rhythm, impaired consciousness, muscle rigidity. Immediately alert a doctor or an emergency medical service if any of these symptoms develop (see Section "Special Warnings").

Do not hesitate to ask your doctor or pharmacist for advice and to inform them of any unwanted and unpleasant side effects, particularly those not mentioned in this package leaflet.

5. HOW TO STORE Dogmatil 200 mg scored tablets

Keep out of the reach and sight of children.

Do not use Dogmatil 200 mg scored tablets after the expiry date indicated on the box.

Store below 30°C.

Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist what to do with unused medicines. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Dogmatil 200 mg scored tablets contain

The active substance is:

Sulpiride base200 mg
for one scored tablet.

The other ingredients are: potato starch, lactose, methylcellulose, hydrated silica, talc, magnesium stearate.

How Dogmatil 200 mg scored tablets are supplied and contents of the outer packaging

Scored tablets (Box of 12).

Marketing Authorization Holder and Operating Company

sanofi-aventis France - 1-13, boulevard Romain Rolland - 75014 Paris - France

Manufacturer

SANOFI WINTHROP INDUSTRIE - 6, boulevard de l'Europe - 21800 Quetigny - France

This leaflet was last approved in November 2009.

THIS MEDICAMENT

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers,
Union of Arab Pharmacists.**