

# DOGMATIL® 50 mg hard capsules sulpiride

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 is and what it is used for
2. What you need to know before you take DOGMATIL
3. How to take DOGMATIL
4. Possible side effects
5. How to store DOGMATIL
6. Further Information

## 1. WHAT DOGMATIL IS AND WHAT IT IS USED FOR

### Pharmacotherapeutic group

DOGMATIL belongs to a group of medicines known as neuroleptic antipsychotics. It belongs to the benzamide group.

### Therapeutic indications

This medicine is used:

- In adults: to treat certain forms of anxiety.
- In adults and children over 6 years of age: to treat certain serious behavioral disorders.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOGMATIL

### Contraindications

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

### Never take DOGMATIL in the following situations:

- If you are allergic to the active ingredient (sulpiride) or to any of the other ingredients of DOGMATIL. See Section 6 for a list of ingredients.
- If you have pheochromocytoma (excessive growth of the adrenal glands, which are located at the top of the kidneys and that release substances causing high blood pressure).
- If you have a prolactin-dependent tumor (hormone causing milk secretion), for example, breast cancer or pituitary gland disorders.
- If you are taking another medicine, make sure that it is not contraindicated in combination with DOGMATIL (see "Taking/using other medicines").
- In children younger than 6 years of age because of the risk of choking on the hard capsule.

If you are unsure of anything, do not hesitate to ask your doctor or pharmacist for advice.

### Precautions for use : special warnings

#### Take special care with DOGMATIL

Your doctor may ask you to undergo an electrocardiogram before starting treatment.

This is because this medicine can cause heart rate disorders (see Section 4. "Possible side effects").

- This medicine should be used with caution in the following cases:
  - in elderly patients, particularly if they have dementia,
  - if you have risk factors for stroke (also called "cerebrovascular accident" occurring when blood circulation to a part of the brain is suddenly interrupted),
  - if you or a family member have a history of blood clots, since taking antipsychotic drugs can cause the formation of blood clots.

#### - Inform your doctor:

- if you have a kidney disease (kidney failure), as the dose may be reduced by your doctor,
- if you have heart disease,
- if you have epilepsy, seizures or Parkinson's disease,
- if you have diabetes or if you have risk factors for diabetes.

#### - During treatment:

- if you have muscle stiffness or consciousness disorders with unexplained fever, sweating, paleness, a change in blood pressure or heart rate: stop treatment immediately and consult your doctor urgently.
- if an unexplained fever or infection occurs, your doctor may have you undergo blood tests immediately. This is because this medicine can cause a disturbance in certain blood cells (a decrease in white blood cells) demonstrated by the results of a blood test (see Section 4. "Possible side effects").

#### - Use in children

If your child is taking this medicine, regular medical monitoring is absolutely necessary.

Use of this medicine is not recommended if you have galactose intolerance, Lapp-lactase deficiency or glucose or galactose malabsorption syndrome (rare hereditary diseases).

### Taking/using other medicines

You must never take this medicine in combination with cabergoline, quinagolide or rotigotine (medicines used for lactation disorders), mequitazine (medicine used to treat allergic rhinitis or hives), citalopram or escitalopram (medicines used to treat anxiety or depression) (see "Never take DOGMATIL in the following situations").

Ask your doctor or pharmacists if you are unsure of anything. You must avoid taking this medicine with:

- certain medicines used to treat Parkinson's disease (amantadine, apomorphine, bromocriptine, entacapone, lisuride, pergolide, priribedil, pramipexole, rasagiline, ropinirole, selegiline),
- levodopa,
- certain medicines that can cause serious heart rate disorders (torsades de pointes) such as:
  - medicines used to treat irregular heart beat (class Ia antiarrhythmic such as quinidine, hydroquinidine, disopyramide and class III antiarrhythmics such as amiodarone, dronedarone, sotalol, dofetilide and ibutilide),
  - certain medicines used to treat psychiatric disorders (amisulpride, chlorpromazine, cyamemazine, droperidol, flupentixol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sultopride, tiapride, zuclophentixol),
  - certain antiparasitic agents (halofantrine, lumefantrine, pentamidine),
  - a medicine used to fight dependence on certain drugs (methadone),
  - and other medicines such as: arsenic compounds, bepridil, cisapride, diphemanil, dolasetron IV, erythromycin IV, levofloxacin, mizolastine, prucalopride, vincamine IV, moxifloxacin, spiramycin IV, toremifene.
- medicines containing alcohol.

Tell your doctor or pharmacist if you are using or have recently used another medicines, including medicines obtained without a prescription.

### Food and drink

As with all antipsychotics from this group, you must avoid drinking alcoholic beverages during your treatment.

### 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.

If you take DOGMATIL during the last 3 months of your pregnancy, the following symptoms may occur in your baby: tremor, muscle stiffness and/or muscle weakness, drowsiness, agitation, breathing problems, feeding problems.

If your baby has any of these symptoms, contact your doctor quickly.

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

This medicine can cause drowsiness. You must be careful if you drive or use machines.

**Important information about some of the ingredients of DOGMATIL**  
This medicine contains lactose.

## 3. HOW TO TAKE DOGMATIL

### Dosage

#### For use in adults and children over 6 years of age only.

Always take the dose prescribed by your doctor. If you are unsure of anything, consult your doctor or your pharmacist. The dosage varies and should be adapted to each patient.

Do not stop the treatment of your own accord.

### Method of administration

This medicine is to be taken orally. Swallow the hard capsule(s) with a little water.

### Duration of treatment

Follow your doctor's prescription.

#### If you take more DOGMATIL than you should

You or a family member or friend must imperatively call a doctor or an emergency medical service, as serious heart disorders may occur.

#### If you forget to take DOGMATIL

Do not take a double dose. Take the next dose at the usual time. If you have forgotten several doses, ask your doctor for advice.

#### 4. POSSIBLE SIDE EFFECTS

As with all medicines, DOGMATIL can cause side effects although not all patients get them.

If you have muscle stiffness and consciousness disorders along with unexplained fever, sweating, paleness or a change in blood pressure or heart rate during treatment, you must stop treatment immediately and urgently seek medical advice.

**The following side effects may also occur:**

- tremor, muscle stiffness, abnormal movements of the tongue and/or face,
- dizziness on standing from a lying or sitting position,
- drowsiness,
- hyperprolactinemia (excessive amounts of prolactin in the blood, which is a hormone that causes lactation) that could cause:
  - in women: absence of menstrual period, swelling of the breasts, secretion of milk outside of normal breastfeeding periods, frigidity (lack of sexual pleasure),
  - in men: impotence (erectile dysfunction).
- weight gain,
- seizures (involuntary contractions of one or more muscles),
- skin rash,
- increase in liver enzymes,
- heart rate disorders that could cause death (see "Take special care with DOGMATIL"),
- swelling, pain or redness of the legs. Blood clots in the veins (particularly in the legs) can move through the blood vessels up to the lungs and cause chest pain and difficulty breathing.
- leukopenia, neutropenia, agranulocytosis (low levels of white blood cells in the blood) (see "Take special care with DOGMATIL"),
- neonatal withdrawal syndrome (see Section "Pregnancy").

**Reporting side effects**

If you have any side effects, immediately talk to your doctor, pharmacist or another health professional (e.g. a nurse). This includes side effects not listed in this leaflet. By reporting side effects, you help improve knowledge about the safety of the medicine.

#### 5. HOW TO STORE Dogmatil

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use DOGMATIL after the expiry date indicated on the box.

Store below 30°C.

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. FURTHER INFORMATION

**What DOGMATIL 50 mg hard capsules contain**

**The active substance is:**

Sulpiride ..... 50 mg  
for one hard capsule.

**The other ingredients are:** lactose, methylcellulose, talc, magnesium stearate. Composition of the hard capsule shell: gelatin, titanium dioxide (E171).

**How DOGMATIL 50 mg hard capsules are supplied and contents of the outer packaging**

This medicine is supplied as hard capsules. Each box contains 30 hard capsules.

**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

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