

# DOGMATIL<sup>®</sup> TABLET

Sulpiride (200mg)

## What is in this leaflet

1. What Dogmatil is used for
2. How Dogmatil works
3. Before you use Dogmatil
4. How to use Dogmatil
5. While you are using it
6. Side effects
7. Storage and Disposal of Dogmatil
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What Dogmatil is used for

- Acute and chronic psychotic disorders, such as
  - schizophrenia
  - chronic non-schizophrenia delusions (a belief that is not true)
  - paranoid delusions
  - chronic hallucinatory psychosis (hearing voices or seeing things which are not there)

## How Dogmatil works

Dogmatil 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 to reduce abnormal behavior.

## Before you use Dogmatil

### - When you must not use it

Do not take Dogmatil if:

- You are allergic (hypersensitive) to sulpiride or to any of the other ingredients of this medicine (listed at the end of this leaflet). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have a tumour on the adrenal gland called pheochromocytoma
- You have breast cancer or cancer in the pituitary gland
- You are taking cabergoline, quinagolide and rotigotine that used to treat Parkinson's disease.
- You are taking mequitazine that used for treatment of allergies and

inflammation of the mucous lining of the nose.

- You are taking citalopram and escitalopram that used for treatment of depression.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Dogmatil.

### - Before you start to use it

Check with your doctor before taking Dogmatil if:

- 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)
- You are elderly
- You have dementia (memory loss and thinking disorder)
- You have Parkinson's disease (movement disorder)
- You have diabetes
- You have epilepsy or have had fits (seizures)
- You are taking levodopa, antiparkinsonian dopamine agonist, antiparasitic agents, methadone, other neuroleptics and medicinal products. (see taking other medicines)
- You have rare genetic problems such as sugar intolerance.

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

### - Taking other medicines

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

- Cabergoline and quinagolide – used to treat Parkinson's disease.

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

- Medicines for antiparasitics (such as halofantrine, lumefantrine or pentamidine)
- Medicines for antiparkinsonian (such as amantadine, apomorphine,

bromocriptine, entacapone, lisuride, pergolide, piribedil, pramipexole, ropinirole, selegiline and levodopa)

- Medicines for an uneven heartbeat (such as sotalol, quinidine, hydroquinidine, disopyramide dofetilide or ibutilide)
- Other medicinal products (such as bepridil, cisapride, diphemanil, mizolastine, vincamine)
- Antibiotics (such as erythromycin, moxifloxacin, spiramycin, azithromycin, clarithromycin)
- Medicines for schizophrenia (such as amisulpride, chlorpromazine, cyamemazine, droperidol, haloperidol, levomepromazine, pimozide, pipotiazine, sertindole, sultopride, tiapride or veralipride)
- Medicine for pain relief and as a drug substitute (methadone)
- Alcohol

#### **The following medicines need extra precaution for use in combination with Dogmatil:**

- Medicines for treat heart failure (bisoprolol, carvedilol, metoprolol, nebivolol)
- Medicines for heart disorders, such as digitalis
- Tetracosactide used to test the function of your adrenal gland
- Glucocorticoids used to lower inflammation
- Water tablets (diuretics) that can lower the levels of potassium in your blood
- Some medicines used for constipation (laxatives)
- Sucralfate used for stomach ulcers
- Medicines for indigestion and heartburn (such as antacids and charcoal)

#### **Your doctor might consider taking precaution with the following medicines in combination with Dogmatil:**

- Blood pressure lowering medicine
- Nitrates, nitrites and related medicines - used to prevent angina (chest pain)
- Medicines for heart rhythm disorders called beta blockers (except esmolol and sotalol)

### How to use Dogmatil

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

- Swallow your tablets orally in whole with plenty of water.

#### - How much to use

If your clinical condition allows, treatment will be initiated at a low dose, followed by gradual increments. The daily dose can be 200 to 1000mg (1-5tablets). The minimum effective dose should always be used.

#### - When to use it

**Take Dogmatil at about the same time each day unless your doctor tells you otherwise.**

#### - How long to use it

**Continue taking your medicine for as long as your doctor tells you.**

#### - If you forget to use it

If you forget to take your tablet, take it as soon as you remember. If it is almost time for your next dose, leave out that dose completely and take the next tablet at the usual time. Do not take a double dose to make up for a forgotten tablet.

#### - If you use too much (overdose)

If you take too many tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: involuntary muscle contraction in the neck area, protrusion of the tongue and lockjaw, Parkinsonian syndrome and coma.

### While you are using it

#### - Things you must do

#### **Pregnancy and breast-feeding**

Tell your doctor immediately if:

- You are pregnant, might become pregnant or think you may be pregnant. The following symptoms may occur in newborn babies, of mothers that have used Dogmatil in the 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.

- You are breast-feeding as sulphiride passes into the breast milk and not recommended during treatment.

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

#### - Things you must not do

- **Do not give this medicine to anyone else, even if they have the same condition as you.**
- **Do not use this medicine to treat any other complaints unless your doctor tells you to.**
- **Do not stop taking Dogmatil, or change the dosage, without checking with your doctor.**
- **Do not drink alcohol while taking Dogmatil because alcohol can increase the effects of Dogmatil.**

#### - Things to be careful of

#### **Driving and using machines**

Dogmatil can make you feel drowsy which may impair your ability to concentrate. If this happens, do not drive, or use any tools or machines.

#### **Important information about some of the ingredients of Dogmatil**

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

#### **Side Effect**

Like all medicines, Dogmatil can cause side effects, although not everyone gets them.

#### **Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

#### **Stop taking Dogmatil Tablets and see a doctor or go to a hospital straight away if:**

- You experience reactions such as rash, itching, fever, difficulty in breathing or wheezing, swelling
- You have movements that you cannot control, mainly of the tongue, mouth, jaw, and eye
- You have fits
- 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 side effect called 'neuroleptic malignant syndrome'

- You have very fast or very slow, uneven or forceful heartbeats. You may also have breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain which can lead to heart stop beating unexpectedly.
- 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.

#### **Tell a pharmacist or doctor as soon as possible if you have any of the following side effects:**

- Feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure)
- Rigid or stiff muscles, trembling or shaking, difficulty moving
- Feeling restless and not being able to keep still (akathisia)

#### **Talk to your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:**

- Abnormal production of nipple discharge
- Weight gain
- Breast enlargement or painful breasts in men
- Loss of menstrual periods
- Difficulty in getting or keeping an erection or in ejaculating (impotence)
- Feeling drowsy or sleepy
- Skin rashes

Other side effects not listed above may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public→Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## Storage and Disposal of Dogmatil

### - Storage

- Keep this medicine in a safe place where children cannot see or reach it.
- Store below 30°C
- Do not use Dogmatil after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

### - Disposal

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.

## Product Description

### - What it looks like

- White to ivory white tablets scored on one side, engraved on the other side.

### - Ingredients:

- Active ingredient:
  - Dogmatil 200mg tablet contains 200mg of sulpiride.
- Inactive ingredients:
  - potato starch, lactose monohydrate, methylcellulose, hydrated colloidal silica, talc, magnesium stearate.

### - MAL Numbers:

MAL19913453AZ

## Manufacturer

Sanofi Winthrop Industrie  
6, boulevard de l'Europe  
21800 Quetigny  
France.

## Product Registration Holder

Sanofi-aventis (Malaysia) Sdn. Bhd.  
Unit TB-18-1,  
Level 18, Tower B, Plaza 33  
No.1 Jalan Kemajuan,  
Seksyen 13,  
46200 Petaling Jaya,  
Selangor Darul Ehsan,  
Malaysia.

## Date of revision

27/07/2017

## Serial Number

BPFK(R4/1)210717/00179