

# Consumer Medicine Information

## MOTETIS

### **Tetrabenazine**

Motetis 25 mg tablets

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### **What is in this leaflet**

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Please read this leaflet carefully before you start using Motetis.

This leaflet answers some common questions about Motetis. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Motetis against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine. You may need to read it again.

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### **What Motetis is used for**

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Motetis is a medicine belonging to the group treating disorders of the nervous system.

Motetis is used for the treatment of diseases causing jerky, irregular, uncontrollable movements (hyperkinetic motor disorders with Huntington's chorea).

Your doctor may have prescribed Motetis for another reason.

Ask your doctor if you have any questions about why Motetis has been prescribed for you.

This medicine is available only with a doctor's prescription.

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### **Before you use Motetis**

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## ***When you must not use it***

Do not use Motetis if:

- if you are allergic (hypersensitive) to tetrabenazine or any of the other ingredients of Motetis 25 mg tablets.
- if you use reserpine (medicine to control high blood pressure and treat psychotic states).
- if you use MAO inhibitors (medicine to treat depression)
- if you suffer from Parkinson-like symptoms
- if you have depression
- if you are breast-feeding
- if you suffer from pheochromocytoma (tumour of the adrenal gland)
- if you suffer from pro-lactin-dependent tumours, e.g. pituitary or breast cancer

If you are not sure whether you should start using Motetis, talk to your doctor.

## ***Before you start to use it***

Tell your doctor if:

- if you are suffering from mild to severe hepatic impairment
- if you have a heart condition known as long QT syndrome or if you have or have had problems with your heart rhythm.
- if you start to have mental changes such as confusion or hallucinations, or develop stiffness in your muscles and a temperature, you may be developing a condition called Neuroleptic Malignant Syndrome. If you have these symptoms please contact your doctor straight away.

If you have not told your doctor about any of the above, tell them before you start using Motetis.

## ***Taking other medicines***

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Motetis.

Some medicines may interfere with Motetis.

Take special care if you use Motetis together with Levodopa (a medicine used to treat Parkinson's disease). Do not use Motetis together with reserpine Treatment with MAO inhibitors should be stopped 14 days before the treatment with tetrabenazine starts.

It is not recommended to use this medicine with certain types of antidepressants, alcohol, opioids, beta blockers, antihypertensive drugs (medicine to treat high blood pressure), hypnotics and neuroleptics (medicine to treat psychotic disorders).

Inhibitors of CYP2D6 (e.g. fluoxetine, paroxetine, terbinafine, moclobemide and quinidine) may result in increased plasma concentrations of the active metabolite dihydrotetrabenazine, and they should only be combined with caution. A reduction of the tetrabenazine dose may be necessary.

Take special care if you use Motetis together with drugs known to prolong the QTc interval in the ECG, including some drug used to treat mental health conditions (neuroleptics), certain antibiotics (e.g. gatifloxacin, moxifloxacin) and some drugs used to treat problems with heart rhythm conditions (e.g. quinidine, procainamide, amiodarone, sotalol).

These medicines may be affected by Motetis, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Motetis.

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## How to use Motetis

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### ***How much to take***

#### **Organic Central Nervous System Movement Disorders**

##### **Adults**

Dosage and administration are variable and only a guide is given. An initial starting dose of 25mg three times a day is recommended. This can be increased by 25mg a day every three or four days until 200mg a day is being given or the limit of tolerance, as dictated by unwanted effects, is reached, whichever is the lower dose.

If there is no improvement at the maximum dose in seven days, it is unlikely that the compound will be of benefit to the patient, either by increasing the dose or by extending the duration of treatment.

##### **Tardive Dyskinesia**

Recommended starting dose of 12.5mg a day subsequently titrated according to response. Medication should be discontinued if there is no clear benefit or if the side-effects cannot be tolerated.

##### **The elderly**

The standard dosage has been administered to elderly patients without apparent side effects. However, Parkinson-like side effects are common.

**Children**

The treatment is not recommended in children.

**Patients with hepatic disorder**

Patients with mild to moderate hepatic disorders should start with half a tablet a day. For patients with severe hepatic disorders, additional caution is necessary.

**Patient with renal disorder**

Motetis is not recommended for use in this patient group.

Swallow the tablet(s) with water or another non-alcoholic drink.

***When to take it***

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

***How long to take it***

Do not stop taking Motetis unless your doctor tells you to. A neuroleptic malignant syndrome has been described after abrupt withdrawal of tetrabenazine.

***If you forget to take it***

If you forget to take one dose, you should never make up for the missing dose by doubling it at the next time. Instead you should simply continue with the next dose when it is due.

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**While you are using Motetis**

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***Things you must do***

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Motetis.

***Things you must not do***

Do not give Motetis to anyone else, even if they have the same condition as you.

Do not stop taking Motetis unless your doctor tells you to. A neuroleptic malignant syndrome has been described after abrupt withdrawal of tetrabenazine.

## ***Things to be careful of***

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

Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will decide after taking all risks and benefits into account, if you may use Motetis during pregnancy. Motetis must not be taken by breast feeding mothers.

### **Driving and using machines**

Motetis may cause drowsiness and therefore may modify your performance at driving and using machines to a varying degree, depending on the dose and individual susceptibility.

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## **In case of overdose**

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### ***If you take too much (overdose)***

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Motetis.

Do this even if there are no signs of discomfort or poisoning.

Signs and symptoms of overdosage may include: nausea, vomiting, diarrhoea, drowsiness, sweating, hypotension, confusion, hallucinations, hypothermia and sedation. Treatment is symptomatic.

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## **Side Effects**

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Motetis.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

The following undesirable effects are ranked according to system organ class and to their frequency:

very common: affects more than 1 user in 10

common: affects 1 to 10 users in 100

uncommon: affects 1 to 10 users in 1,000

rare: affects 1 to 10 users in 10,000

very rare: affects less than 1 user in 10,000

not known: frequency cannot be estimated from the available data

**Very common:**

Drowsiness (with higher dosages), depression, Parkinson-like syndrome (uncontrollable movements of the hands, arms, legs and head, with higher dosages)

**Common:**

Confusion, anxiety, sleeplessness, low blood pressure, dysphagia (difficulty in swallowing), nausea, vomiting, diarrhoea, obstipation

**Uncommon:**

Mental changes such as confusion or hallucinations, muscular rigidity, fever, autonomic dysfunction

**Rare:**

Neuroleptic malignant syndrome (NMS) (neurological disorder)

**Very rare:**

Skeletal muscle damage

For the following side-effects, it is not possible to estimate the incidence from available data: Disorientation, nervousness, ataxia, akathisia, dystonia, dizziness, amnesia, bradycardia, epigastric pain, dry mouth

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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## **After using Motetis**

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### ***Storage***

Keep out of the reach and sight of children.

Do not use Motetis after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. This medicinal product does not require any special temperature storage conditions.

### ***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.

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## Product description

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### *What it looks like*

Yellow, round, flat tablets with a scoreline on one side packaged in white twist-off bottles with 112 tablets.

### *Ingredients*

#### Active ingredient(s):

- Each tablet contains 25 mg tetrabenazine

#### Inactive ingredients:

- The other ingredients are: pregelatinised maize starch, lactose monohydrate, talc, iron oxide yellow E172, magnesium stearate.

These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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## Sponsor Details

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Motetis is supplied in New Zealand by:

Douglas Pharmaceuticals Limited  
PO Box 45 027  
Auckland 0651  
NEW ZEALAND

ph: (09) 835 0660

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## Date of Preparation

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This leaflet was prepared on 12 July 2011.