

Package leaflet: Information for the patient

Tetrabenazine Aristo 25 mg tablets

Tetrabenazine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tetrabenazine Aristo is and what it is used for
2. What you need to know before you take Tetrabenazine Aristo
3. How to take Tetrabenazine Aristo
4. Possible side effects
5. How to store Tetrabenazine Aristo
6. Contents of the pack and other information

1. What Tetrabenazine Aristo is and what it is used for

Tetrabenazine Aristo contains the active substance tetrabenazine. This affects some of the chemicals that are released by the nerves in the brain which helps to control jerky and irregular movements of the body (called chorea).

It is used for the treatment of jerky, irregular uncontrollable movements that can be caused by conditions such as Huntington's chorea.

It is also used for the treatment of tardive dyskinesia.

- Tardive dyskinesia is a condition characterised by uncontrollable movements such as facial spasm, grimacing or particular tongue movements.
- Some medicines used to treat certain mental health conditions (antipsychotics) can cause tardive dyskinesia.
- It should only be given to you for treatment of tardive dyskinesia when symptoms are moderate to severe, disabling, and/or embarrassing in social situations.
- It should only be given to you when symptoms persist even after your doctor has stopped, changed, or reduced the dose of your antipsychotic medication.

2. What you need to know before you take Tetrabenazine Aristo

Do not take Tetrabenazine Aristo

- if you are allergic to tetrabenazine or any of the other ingredients of this medicine (listed in section 6);
- if you have thoughts of self-harm or suicide;
- if you suffer from depression or if your symptoms persist despite antidepressant treatment;
- if you have a prolactin (a hormone)-dependent tumour, such as breast cancer or a tumour of the pituitary gland (pituitary prolactinoma);
- if you have a tumour of the inner adrenal gland (phaeochromocytoma);
- if you are breast-feeding;
- if you are taking certain antidepressants (monoamine oxidase inhibitor) , or have taken one within the last 14 days;
- if your liver function is impaired;

- if you are taking medicines containing reserpine as active substance;
- if you are suffering from Parkinson's disease or Parkinson's symptoms.

Warnings and precautions

Talk to your doctor before taking tetrabenazine

- if you have been diagnosed with depression or have thought about or tried to commit suicide;
- if you have ever had depression.

Treatment of tardive dyskinesia (delayed movement disorders)

Ask your doctor whether you can be considered for treatment with Tetrabenazine Aristo. He/she will advise you accordingly. However, tetrabenazine is a centrally-acting, transmitter-depleting substance which, in humans, may also cause extrapyramidal symptoms and, theoretically, tardive dyskinesia.

Onset of depression (morbidly depressed mood) / suicidality (thoughts or behaviour of taking their own lives)

Tetrabenazine can cause depression or worsen pre-existing depression.

If depression occurs, it may possibly be controlled by dose reduction. There have been isolated cases where patients taking tetrabenazine have developed thoughts of taking their own lives (suicidal thoughts) or have shown suicidal behaviour.

If marked depression or suicidal thoughts occur, tetrabenazine should be discontinued and antidepressant therapy started.

If you experience depression during treatment with this medicine, please tell your doctor. He/she will take the necessary steps.

Anger and aggressive behaviour

In patients taking tetrabenazine with depression or a history of other psychiatric illnesses, there is a potential risk of developing or worsening anger and aggressive behaviour.

Onset of Parkinson's symptoms

Tetrabenazine Aristo can trigger Parkinson's symptoms and worsen pre-existing symptoms of Parkinson's disease. If this happens to you, please inform your doctor. He/she will take the necessary steps.

Dysphagia

Dysphagia is a component of Huntington's disease. However, medicines that reduce dopaminergic transmission have been associated with esophageal dysmotility (a disorder of motility in the esophagus) and dysphagia (swallowing disorder). Dysphagia may be associated with aspiration pneumonia (a kind of pneumonia caused by aspiration of foreign bodies or liquids). If you notice difficulties in swallowing ask your doctor for advice.

Onset of neuroleptic malignant syndrome

During treatment with this medicine, so-called neuroleptic malignant syndrome (NMS) may occur in rare cases.

This is a condition that is life-threatening in rare cases, in which high fever, sweating, blood pressure fluctuations, irregular or rapid pulse, heart rhythm disorders, muscle stiffness and impaired consciousness occur.

If you experience one or more of these symptoms, you must contact your doctor or nearest hospital immediately.

Patients with a history of tumours

If this medicine is taken over a prolonged period of time, concentrations of prolactin (a hormone) in the blood may increase. This higher concentration can, in rare cases, promote the growth of cells in breast tumours. For this reason, please tell your doctor before taking this medicine if you have a history of any tumours.

Patients with prolonged QT interval

Tetrabenazine leads to a slight prolongation of the QT interval in the ECG. Caution must therefore be exercised in patients with congenital long QT syndrome and with a history of heart rhythm disorders, or in patients taking other medicines that can prolong the QT interval.

Cardiac disease

Tell your doctor if you recently had heart problems as myocardial infarction or unstable cardiac disease.

Restlessness and agitation

Tell your doctor if you notice any difficulties in maintaining a sitting or standing position for prolonged periods of time (inability to sit still), or suffer from restlessness or increased fidgeting. These side effects may make it necessary to reduce your dose.

Sedation and somnolence

Tetrabenazine may cause sedation (calming effect) or somnolence (drowsiness or abnormal tiredness). In this case, you should refrain from activities that require special alertness (e.g. driving or operating hazardous machinery).

Orthostatic hypotension

A drop in blood pressure may occur under certain conditions in patients treated with Tetrabenazine Aristo (e.g. when getting up from lying down). Tell your doctor if you have been told you have low blood pressure (associated with symptoms such as dizziness, headache, racing heart or collapse).

Binding to melanin-containing tissues

Tetrabenazine and its metabolites may bind to melanin-containing tissues, where they accumulate over time. It is therefore possible that tetrabenazine may cause damage to these tissues with long-term use. Although there are no specific recommendations for regular eye tests, prescribing doctors should be aware of the possible effects of long-term use of tetrabenazine on the eyes. The clinical relevance of tetrabenazine binding to melatonin-containing tissues is unknown.

Laboratory tests

In clinical studies with tetrabenazine, no clinically significant changes in laboratory parameters were reported. In controlled clinical studies, tetrabenazine caused a slight increase in ALT and AST laboratory values compared to placebo.

Other medicines and Tetrabenazine Aristo

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription.

If taken at the same time, the following medicines may interact with Tetrabenazine Aristo:

- Reserpine: tetrabenazine must not be taken at the same time as reserpine. If treatment with reserpine is to be switched to tetrabenazine, this must be done carefully and with a sufficient interval of several days.
- MAO inhibitors (certain antidepressants): To avoid the risk of a potential serious interaction resulting in hypertensive crisis, care must be taken to ensure that there is an interval of at least 14 days between stopping this medicine and starting treatment with a MAO inhibitor, as well as between stopping the MAO inhibitor and starting treatment with Tetrabenazine Aristo.
- Medicines that prolong the QT interval in the ECG, e.g. neuroleptics, certain antibiotics (gatifloxacin, moxifloxacin), certain antiarrhythmics (quinidine, procainamide, amiodarone, sotalol)
- Medicines for high blood pressure (antihypertensives) and beta-blockers (medicines that reduce heart rate and blood pressure)
- Medicines with a sedative effect in the brain, e.g. neuroleptics, hypnotics and opioids
- Levodopa, a medicine for Parkinson's disease
- Certain medicines that slow the breakdown of tetrabenazine, e.g. fluoxetine, paroxetine, quinidine, duloxetine, terbinafine, amiodarone, sertraline
- Medicines broken down via CYP2D6 (e.g. metoprolol, amitriptyline, imipramine, haloperidol and risperidone): the effects of these medicines may be enhanced. Additional use of medicines that inhibit CYP2D6 (e.g. fluoxetine, paroxetine, quinidine, duloxetine, terbinafine, amiodarone or sertraline) may additionally increase this effect.

Tetrabenazine Aristo with alcohol

The sedative effect of this medicine may be enhanced if alcohol is consumed at the same time.

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 or pharmacist for advice before taking this medicine.

Pregnancy

There are no adequate data on the safety of tetrabenazine in pregnant women. Therefore, Tetrabenazine Aristo is not recommended for use during pregnancy or in women of childbearing potential not using contraception.

Breast-feeding

It is unknown whether tetrabenazine is excreted in human milk. A risk to the suckling child cannot be excluded. Tetrabenazine Aristo is contraindicated during breastfeeding.

Fertility

Tetrabenazine prolonged female cycles and delayed fertility in animals.

Driving and using machines

This medicine may cause drowsiness. This may affect your ability to drive or use machines. You should talk to your doctor about the effects of this medicine on your ability to drive, as the degree of impairment may differ greatly between individuals.

Tetrabenazine Aristo contains lactose

Each tablet contains 63.4 mg lactose (as lactose monohydrate).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Tetrabenazine Aristo

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

When starting treatment, your doctor will slowly increase your dose over several weeks to find a dose for chronic use that reduces your symptoms and is well-tolerated.

Your dose will depend on your symptoms and your response to treatment. The required dose may vary from patient to patient. The following dose recommendations are therefore only a guide.

Your doctor will review your dose at regular intervals once a stable maintenance dose has been achieved.

Adults

Uncontrollable movements caused by conditions such as Huntington's chorea:

- The recommended starting dose is half a tablet (12.5 mg) to one tablet (25 mg) every day.
- The dose is usually increased gradually by your doctor. The maximum daily dose is eight tablets (a total of 200 mg), depending on any side effects you may experience.
- Tablets should then be taken two or three times daily, as instructed by your doctor.

Tardive Dyskinesia:

- The recommended starting dose is half a tablet (12.5 mg) a day, which may be increased by your doctor as needed depending on your response to treatment.

Resumption of treatment

If your treatment was interrupted for more than 5 days or interruption of your treatment was necessary due to a medical condition or due to concomitant use of other medicines, your tetrabenazine therapy should be retitrated when resumed. Depending on your doctor's instruction, your dose should be started at

12.5mg twice a day This low dose will be kept for 7 days and then your dose will be increased in steps of 12.5mg per day.

If you notice adverse reactions such as inability to sit still (akathisia), restlessness, parkinson's symptoms such as impaired balance, tremors or increased salivation, depression, insomnia, anxiety or an intolerable sedation occurs, contact your doctor.

Your doctor will decide whether your titration should be stopped and the dose should be reduced.

Special populations

Elderly patients

No specific studies have been conducted. Elderly patients usually receive the dose recommended for adults.

Patients with liver or kidney impairment

If you have problems with your liver or kidneys, your doctor may prescribe a different dosing schedule and/or a different dose.

Talk to your doctor before taking tetrabenazine if you know you are a slow or medium-fast metaboliser of an enzyme called CYP2D6. In this case, you may require a different dose.

Children

No specific studies have been conducted.

The treatment is not recommended in children.

Method of administration

Tetrabenazine Aristo is for oral use.

Take the tablets with sufficient liquid (water or other non-alcoholic beverages. Do not take the tablets with alcohol) and do not chew them.

The tablets have a score line and can be divided into equal doses.

If you take more Tetrabenazine Aristo than you should

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

Symptoms of overdose include uncontrollable muscle spasms affecting the eyes, head, neck and body, uncontrolled rolling of the eyes, excessive eye blinking, nausea, vomiting, diarrhoea, sweating, dizziness, feeling cold, confusion, hallucinations, drowsiness, redness/inflammation and tremor.

If you forget to take Tetrabenazine Aristo

Do not take a double dose to make up for a forgotten dose.

Continue treatment with the next dose as normal.

If you stop taking Tetrabenazine Aristo

Your doctor will decide when your treatment can be stopped. He may decide to gradually reduce the dose, although it may not be necessary. This is usually done so you avoid side effects that may arise as a result of suddenly stopping your medication.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Please seek advice immediately or go to your emergency department if you experience the following side effects:

- If you experience muscle stiffness, fever or impaired consciousness (e.g. confusion or hallucinations), stop taking the tablets. Consult your doctor or nearest hospital as soon as possible

(see also section 2 “Warnings and precautions”).

- Very common (may affect more than 1 in 10 people): Tetrabenazine Aristo can cause depression, which can, in some people, lead to thoughts of committing suicide. If you feel down or very sad you may be starting to become depressed and you should tell your doctor about this change.
- Very rare (may affect up to 1 in 10,000 people): if you have tried to commit suicide or if you have intentionally hurt yourself or if you have started to think about intentionally hurting yourself.

Other possible side effects:

Very common: may affect more than 1 in 10 people

- depression (which has been associated in some cases with suicidal thoughts and suicidal behaviour)
- drowsiness
- Parkinson’s symptoms such as impaired balance, tremors or increased salivation

Common: may affect up to 1 in 10 people

- agitation
- confusion
- feeling of anxiety
- sleeplessness
- decreased appetite

Very rare: may affect up to 1 in 10,000 people

- pneumonia
- reduction in the number of white blood cells (leukopenia)
- involuntary rolling of the eyes (oculogyric crisis)
- aversion to light (photophobia)
- dehydration
- aggression, anger
- suicidal thoughts
- neuroleptic malignant syndrome (a condition where high fever, sweating, blood pressure fluctuations, muscle stiffness and impaired consciousness occur), see section 2 “Warnings and precautions”
- rash, itching, hives
- weight loss
- increased risk of falling

Not known: frequency cannot be estimated from the available data

- disturbance of balance regulation and movement coordination (ataxia)
- inability to sit still (akathisia)
- movement disorder with involuntary spasms and abnormal postures (dystonia)
- impaired memory performance
- dizziness
- disorientation
- nervousness
- restlessness
- sleep disturbances
- slow heart beat (bradycardia)
- drop in blood pressure with dizziness on standing up (orthostatic hypotension)
- hypertensive crisis
- swallowing difficulties
- nausea (feeling sick)
- vomiting
- pain in the upper abdomen
- diarrhoea
- constipation
- dry mouth
- sweating
- irregular monthly periods

- tiredness
- weakness
- reduced body temperature (hypothermia)
- increased appetite
- weight increase

If Tetrabenazine Aristo is taken for prolonged periods, the concentration of prolactin (a pituitary gland hormone) in your blood may increase. This returns to normal after treatment is stopped. As a result, abnormal breast milk discharge (galactorrhoea), absent or irregular monthly periods, male breast enlargement (gynaecomastia), breast pain, breast enlargement, pituitary tumours (prolactinomas), orgasmic disorders and impotence may occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tetrabenazine Aristo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from light.

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. Contents of the pack and other information

What Tetrabenazine Aristo contains

- The active substance is tetrabenazine.
- The other ingredients are: lactose monohydrate (see section 2 “What you need to know before you take Tetrabenazine Aristo”), maize starch, microcrystalline cellulose, talc, magnesium stearate, yellow iron oxide (E172).

What Tetrabenazine Aristo looks like and contents of the pack

Tetrabenazine Aristo 25 mg tablets are pale yellow and round with a score line on one side and with an approximate diameter of 7.00 mm ± 0.2 mm.

The tablet can be divided into equal doses.

Tetrabenazine Aristo is available in bottles of 112 tablets.

Marketing Authorisation Holder and Manufacturer

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