

Package leaflet: Information for the patient

Lorazepam Aristo 1 mg orodispersible tablets Lorazepam Aristo 2.5 mg orodispersible tablets

Lorazepam

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

1. What Lorazepam is and what it is used for

Lorazepam Aristo contains the active substance lorazepam, which is a sedative and anti-anxiety medicine (tranquilliser). It belongs to the benzodiazepine group of active substances.

What it is used for

- Symptomatic short-term treatment of anxiety and sleep disorders caused by anxiety where the anxiety is severe, disabling or subjecting the individual to unacceptable distress.
- Sedation prior to diagnostic procedures, as well as before surgical interventions

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

Do not take Lorazepam Aristo

- if you are allergic to lorazepam, benzodiazepines or any of the other ingredients of this medicine (listed in section 6)
- if you have, or have ever had, an addiction to any medicines, alcohol or drugs
- if you have severe breathing problems, e.g. chronic obstructive pulmonary disease
- if you have abnormal muscle weakness (myasthenia gravis)
- if you have serious liver problems
- if you suffer from breathing problems when you are asleep (sleep apnoea syndrome)
- in case of acute poisoning with alcohol or depressants affecting the Central Nervous System (CNS) (e.g. sleeping pills or painkillers, medicines for the treatment of mental disorders, such as antipsychotics, antidepressants and lithium)
- if you are under 6 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lorazepam Aristo if:

- you have problems with controlling your movements (spinal or cerebellar ataxia)
- you suffer from breathing problems, e.g. chronic obstructive lung disease

- you have kidney or liver problems
- you are suffering from an eye problem called glaucoma e.g. high pressure within the eye
- you abuse or have in the past abused drugs or alcohol
- you have a personality disorder; it may mean you have a greater chance of becoming dependent upon Lorazepam
- you have suffered from depression before, as it might come back during Lorazepam treatment
- you are suffering from depression, as Lorazepam may increase any suicidal feelings or thoughts you may have
- you are elderly, you may be more likely to fall
- you have low blood pressure.

Some patients have experienced **suicidal thoughts** whilst taking medicines containing lorazepam, particularly if they are already depressed. If you are depressed, have irrational fears and obsessions, have started experiencing thoughts of suicide or harm towards yourself, please tell your doctor immediately.

At the start of therapy, your doctor will monitor your individual response to this medicine, so that a potential overdose can be detected as quickly as possible. If you are a child, an older or debilitated patient, you may show a more sensitive response to the effects of Lorazepam Aristo. Therefore, your therapy should be monitored more frequently.

If you suffer from kidney or liver dysfunction, have existing heart failure and/or low blood pressure (hypotension), you may have greater sensitivity to the effects of this medicine; the same applies if you are elderly. You may be at greater risk of falls, especially when you get up at night.

Hepatic encephalopathy (brain disease due to liver damage) may occur with the use of lorazepam. Lorazepam must therefore not be used in patients with severely impaired liver function and/or hepatic encephalopathy.

You may observe memory loss during treatment with lorazepam.

When used as a sleeping tablet, you should ensure that you get a sufficient amount of sleep (about 7 to 8 hours). If you follow this recommendation, the after-effects the next morning can usually be avoided (e.g. tiredness, impaired reaction skills).

Please ask your doctor to give you more detailed instructions on how to go about your everyday life, taking your particular lifestyle into account (e.g. occupation).

There have been uncommon reports of paradoxical reactions occurring with the use of benzodiazepines such as anxiety, states of agitation, delusion, excitability, aggressive behaviour sleep disorders, sexual arousal, hallucinations, psychoses(see section 4.). Such reactions are more likely if you are a child or an elderly patient. Treatment with lorazepam should be stopped if paradoxical reactions occur.

Potentially fatal respiratory depression may occur with use of benzodiazepines including lorazepam.

When taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take Lorazepam Aristo for as short a period of time as possible (see section 4).

If after a few weeks you notice that the medicine is not working as well as it did when first starting treatment, you should speak to your doctor.

Treatment with Lorazepam Aristo should be discontinued gradually to avoid withdrawal symptoms. See section 3 'If you stop taking Lorazepam Aristo'.

Severe allergic reactions have been reported with benzodiazepine use. Cases of swelling of the skin and/or mucous membranes involving the tongue, larynx or vocal cord region (angioedema) have been

reported in patients after taking the first dose or subsequent doses of benzodiazepines. Some patients have experienced other symptoms while taking benzodiazepines, such as shortness of breath (dyspnoea), swelling of the throat or feeling and being sick.

Some patients had to be treated as a medical emergency. If these symptoms occur, please tell your doctor immediately or go to hospital straight away. The airways can become blocked, which may prove fatal.

Children and adolescents

Children and adolescents under 18 years should not be treated with Lorazepam unless it is urgently required for sedation before surgery or before diagnostic procedures. For children under 6 years, Lorazepam is contraindicated. Further information can be found in section 3.

Other medicines and Lorazepam Aristo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- Medicine for narcolepsy with cataplexy (e.g. sodium oxybate)
- Medicine for treating HIV (e.g. zidovudine)
- Medicine to treat delusions or hallucinations (e.g. chlorpromazine, loxapine or clozapine)
- Medicine to help with indigestion (e.g. antacids, cisapride or omeprazole)
- A medicine to control nausea and vomiting induced by chemotherapy called nabilone
- Medicines for addiction treatment (e.g. lofexidine and disulfiram)
- Strong pain killers (e.g. methadone, tramadol, codeine, morphine)
- Medicines used to treat tuberculosis such as isoniazid
- Antibiotics such as erythromycin
- Medicines to treat high blood pressure (e.g. ACE-inhibitors, alpha-blockers, angiotensin-II receptor antagonists, calcium channel blockers, adrenergic neurone blockers, beta-blockers, moxonidine, nitrates, hydralazine, minoxidil, sodium nitroprusside and diuretics)
- Medicines used to treat asthma (e.g. theophylline)
- Muscle relaxants (e.g. baclofen and tizanidine)
- Other sedatives (e.g. barbiturates or antihistamines)
- Other medicines used to treat anxiety
- Medicines used to treat depression
- Antihistamines for allergy
- Medicines for Parkinson's disease e.g. levodopa
- Medicines for epilepsy (e.g. phenobarbital or valproate/valproic acid)
- Medicine for gout called probenecid
- Oestrogen-containing contraceptives
- Medicines which affect liver enzymes (e.g. cimetidine, esomeprazole, rifampicin, ketoconazole, itraconazole).

If Lorazepam Aristo is used at the same time as other medicines that depress the central nervous system (e.g. psychotropic agents, sleeping tablets, sedatives, anaesthetics, beta-blockers, opiate-type painkillers, sedative antihistamines, antiepileptics), there may be some interaction, causing additive depressant effects on the central nervous system.

Concomitant use of Lorazepam Aristo and opioids (e.g. strong pain killers, some cough medicines and medicines for substitution therapy) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Lorazepam Aristo together with opioids, the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to

inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The effect of medicines to reduce muscle tension (muscle relaxants) and painkillers may be increased.

If lorazepam is used at the same time as clozapine, marked sedation, excessive salivation and impaired movement coordination may occur.

Administration of Lorazepam Aristo at the same time as valproic acid/sodium valproate can increase the levels of lorazepam in the blood. If valproic acid/sodium valproate is used at the same time, the dose of Lorazepam Aristo should be reduced by about a half.

Administration of Lorazepam Aristo at the same time as probenecid may speed up the onset of action or prolong the effect of lorazepam. If used at the same time as probenecid, the dose of Lorazepam Aristo should be halved.

The use of theophylline or aminophylline can reduce the sedative effect of Lorazepam Aristo.

Lorazepam Aristo with food, drink and alcohol

You should avoid drinking alcohol, as alcohol can alter and increase the effects of Lorazepam Aristo in an unpredictable way.

Grapefruit juice and drinks containing caffeine should be avoided as they can affect the way that Lorazepam works.

Pregnancy and breast-feeding

Pregnancy

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.

Lorazepam Aristo should not be taken during pregnancy. Your doctor will decide if the treatment should be discontinued.

If you take Lorazepam during late pregnancy or during labour, your baby may be less active than other babies, have lower muscular tone, low body temperature (hypothermia) and/or low blood pressure (hypotension), respiratory depression, apnoea and drinking difficulties ("floppy infant syndrome"). Your baby may also develop withdrawal symptoms after birth, if you take Lorazepam Aristo for a prolonged time in the late stages of your pregnancy.

Breast-feeding

As Lorazepam passes into breast milk and might cause sedation and inability to suckle in your baby, you should not take Lorazepam Aristo during breast-feeding.

Driving and using machines

Even when Lorazepam Aristo is used as directed, you should expect your reaction skills to be impaired, especially during the first few days of treatment. In this case, you will no longer be able to react quickly enough to unexpected and sudden events. Do not drive a car or any other vehicle. Do not use any hazardous electrical tools or machines. Do not work without a secure foothold. In particular, please remember that alcohol will further impair your ability to react.

The decision as to what extent driving or other hazardous activities are possible will be taken by your treating doctor, taking your individual response and dosage into consideration.

Lorazepam Aristo contains lactose.

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 Lorazepam Aristo

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

The dose and duration of treatment must be adjusted to your individual response to therapy, the therapeutic indication (i.e. the illness for which this medicine has been prescribed) and the severity of your illness. As a basic rule, the dose should be kept as low as possible and the duration of treatment as short as possible.

Dose

Please follow the directions for use at all times, as Lorazepam Aristo may otherwise not work properly.

The following information applies, unless Lorazepam Aristo has been prescribed otherwise by your doctor:

Treatment of anxiety and sleep disorders caused by anxiety:

The daily dose for adults is generally 0.5 to 2.5 mg lorazepam, divided into 2 to 3 single doses or as a single evening dose. In individual cases, especially in a hospital setting, the doctor may increase the daily dose to a maximum of 7.5 mg lorazepam, taking all precautions into consideration.

If the main focus involves sleep disorders requiring treatment, the daily dose (0.5 to 2.5 mg lorazepam) can be taken as a single dose approximately half an hour before bedtime.

When used as a sleeping tablet, you should take it about half an hour before bedtime; otherwise, it will probably take longer for it to take effect and – depending on the length of sleep – will probably cause more severe after-effects the next morning.

If you take your whole dose in the evening, it should not be taken on a full stomach.

Sedation prior to diagnostic procedures, as well as before surgical interventions:

For adults, 1 to 2.5 mg lorazepam in the evening before surgery and/or 2 to 4 mg lorazepam approximately 1 to 2 hours before the procedure.

The orodispersible tablets can be taken with or without meals.

Use in elderly or debilitated patients

In elderly or debilitated patients, as well as in patients with organic brain changes, the initial total daily dose should be reduced by approximately 50 %. These patients should preferably use preparations with a lower active substance content. The dose must be adjusted by the doctor, depending on the required effect and tolerability in each individual case.

Use in patients with impaired renal function

Patients with kidney problems may be given lower doses. The starting dose is usually half of the recommended normal adult dose. Your doctor will see how you respond to the medicine and alter the dose if needed.

Use in patients with impaired hepatic function

Patients with moderate to mild liver problems may be given lower doses. The starting dose is usually half of the recommended normal adult dose.

Lorazepam is contraindicated in patients with severe liver insufficiency (see section 4.3).

Use in children and adolescents

Lorazepam Aristo should not be used for the treatment of anxiety or insomnia in children and adolescents under 18 years of age.

Aged less than 6 years:

Children under the age of six must not be treated with Lorazepam.

Aged 6 – 12 years:

Before diagnostic procedures or before surgical interventions: The recommended dose is between 0.5 mg to 1 mg, depending upon the weight of the child (0.05 mg/kg body weight dose should not be exceeded), taken at least one to two hours before the operation.

Aged 13 – 18 years of age:

Before diagnostic procedures or before surgical interventions: The recommended dose is between 1 mg to 4 mg, taken one to two hours before the operation.

Method of administration

Lorazepam Aristo is for oral use.

The orodispersible tablets dissolve instantly in the mouth. They can, if desired, be swallowed and washed down with some liquid.

The tablet can be divided into equal doses.

Duration of use

The duration of treatment will be determined by your doctor.

For acute illnesses, the use of Lorazepam Aristo should be limited to single doses or for a few days.

For chronic illnesses, the duration of use will depend on the progression of your illness. After 2 weeks of daily intake, the doctor should clarify by gradual dose reduction whether treatment with Lorazepam Aristo is still indicated.

If you take more Lorazepam Aristo than you should

Tell a doctor immediately if you suspect that intoxication has occurred after quite large amounts of this medicine have been taken. You must call a doctor for first-aid instructions, which you must then apply. Do not induce vomiting unless expressly told to do so.

Signs of an overdose are: drowsiness, confusion, somnolence, shallow breathing, impaired movement coordination, apathy and, in severe cases, unconsciousness.

If you forget to take Lorazepam Aristo

If you forget to take an orodispersible tablet, take it as normal at your next time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lorazepam Aristo

If you suddenly stop your treatment after prolonged use, the withdrawal symptoms mentioned in section 4 may occur. To avoid these symptoms, treatment will be discontinued by gradual dose reduction.

It should be noted that, after prolonged periods of use (more than 1 week) and upon abrupt withdrawal of this medicine, sleep disorders, states of anxiety and tension, inner restlessness and agitation may temporarily return in exaggerated form. Treatment should therefore not be stopped abruptly, but rather discontinued by gradual dose reduction.

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.

Side effects are to be expected especially at the start of treatment, if the dose is too high and in the patient groups mentioned in “Warnings and precautions” (see section 2).

Very common: may affect more than 1 in 10 patients treated

- sedation, tiredness, drowsiness

Common: may affect up to 1 in 10 patients treated

- unsteady movements and gait (ataxia)
- confusion
- depression, onset of depression
- feeling dizzy
- muscle weakness, feeling weary (lassitude)

Uncommon: may affect up to 1 in 100 patients treated

- altered sex drive, impotence, less intense orgasm
- feeling sick

Rare: may affect up to 1 in 1,000 patients treated

- rash
- reduced alertness
- salivation changes

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

- leucopenia

Not known: frequency cannot be estimated from the available data

- changes in blood counts (thrombocytopenia, agranulocytosis, pancytopenia)
- prolonged reaction times
- impaired movement coordination (extrapyramidal symptoms)
- tremor
- visual disturbances (double vision, blurred vision)
- difficulty in articulating/slurred speech
- headache
- convulsions/seizures
- memory gaps (amnesia)
- disinhibition, euphoria
- coma
- suicidal thoughts/attempt
- impaired attentiveness/concentration
- balance disorders
- vertigo
- paradoxical reactions such as anxiety, states of agitation, delusion, excitability, aggressive behaviour (hostility, aggression, rage), sleep disorders/insomnia, sexual arousal, hallucinations, psychoses. If such reactions occur, treatment with Lorazepam Aristo should be stopped.
- low blood pressure (hypotension), slight drop in blood pressure
- respiratory depression (dose-dependent in severity), breathlessness (apnoea), worsening of sleep apnoea (temporary cessation of breathing during sleep)
- worsening of obstructive pulmonary disease (airway constriction)
- constipation
- increased bilirubin
- jaundice, increase in liver enzymes (transaminases, alkaline phosphatase)
- allergic skin reactions
- hair loss
- hypersensitivity reactions, anaphylactic/anaphylactoid reactions, swelling of the skin and/or mucous membranes (angioedema)

- inappropriate antidiuretic hormone secretion (SIADH)
- low sodium blood levels (hyponatraemia)
- decrease in body temperature (hypothermia)

Benzodiazepines cause dose-dependent depression of the central nervous system.

Dependence/abuse

Even after a treatment period of a few days with daily intake of Lorazepam Aristo, withdrawal symptoms (e.g. sleep disorders, increased dreaming) may occur upon discontinuation of therapy, especially when abrupt. Anxiety, states of tension as well as agitation and inner restlessness may return in exaggerated form. Other symptoms reported after discontinuation of benzodiazepines include headache, depression, confusion, irritability, sweating, depressed mood (dysphoria), , loss of reality, behavioural disorders, , numbness and tingling in the limbs, oversensitivity to light, noise and touch, impaired perception, involuntary movements, nausea, vomiting, diarrhoea, loss of appetite, hallucinations/delirium, convulsions/seizures, tremor, abdominal spasms, muscle pain, states of agitation, palpitations, rapid pulse, panic attacks, dizziness, hyperactive reflexes, short-term memory loss and elevated body temperature. With chronic use of Lorazepam Aristo in patients with epilepsy or those taking other medicines that reduce the seizure threshold (e.g. antidepressants), sudden discontinuation may trigger more frequent seizures. The risk of withdrawal symptoms increases with the length of the preceding treatment and dose. These symptoms can usually be avoided by gradual dose reduction.

There are indications of tolerance development (dose increase due to habituation) with regard to the sedative effect of benzodiazepines.

Lorazepam has an abuse potential. At particular risk are patients with a history of drug and/or alcohol abuse.

What measures must be taken in case of side effects?

Many of the side effects mentioned will wear off during the course of further treatment or when the dose is reduced. If side effects persist, please tell your doctor, who should decide whether to stop treatment. Tell your doctor immediately if you get an unexplained skin rash, skin discolouration or swelling.

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 Lorazepam 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 blister and carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

After dividing the orodispersible tablets: Store any remaining half-tablets in the original package in order to protect from light and moisture. Use within 24 hours.

Do not throw away any medicines via wastewater. 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 Lorazepam Aristo contains

- The active substance is: lorazepam
Lorazepam Aristo 1 mg orodispersible tablets: each tablet contains 1 mg lorazepam
Lorazepam Aristo 2.5 mg orodispersible tablets: each tablet contains 2.5 mg lorazepam
- The other ingredients are:
Lorazepam Aristo 1 mg orodispersible tablets: lactose monohydrate, mannitol, microcrystalline cellulose, crospovidone, magnesium stearate [vegetable],
Lorazepam Aristo 2.5 mg orodispersible tablets: lactose monohydrate, mannitol, microcrystalline cellulose, crospovidone, magnesium stearate [vegetable], yellow iron oxide

What Lorazepam Aristo looks like and contents of the pack

Lorazepam Aristo 1 mg orodispersible tablets: White to off white, circular, flat faced, bevel edged, uncoated orodispersible tablet with a deep breakable score-line on one side and plain on the other side. The tablets can be divided into equal doses.

Lorazepam Aristo 2.5 mg orodispersible tablets: Pale yellow, circular, flat faced, bevel edged, uncoated orodispersible, tablet with a deep breakable score-line on one side and plain on the other side.

The tablets can be divided into equal doses.

Lorazepam Aristo is available in packs of 20, 25, 28, 30, 40, 50, 60 and 500 orodispersible tablets. Not all pack sizes may be marketed.

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