Package leaflet: Information for the patient

Voriconazole Aristo 100 mg film-coated tablets

Voriconazole

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Voriconazole Aristo contains the active substance voriconazole. Voriconazole Aristo is an antifungal medicine. It works by killing or stopping the growth of the fungi that cause infections.

It is used for the treatment of patients (adults and children over the age of 2) with:
- invasive aspergillosis (a type of fungal infection due to *Aspergillus sp*),
- candidaemia (another type of fungal infection due to *Candida sp*) in non-neutropenic patients (patients without abnormally low white blood cells count),
- serious invasive *Candida sp*. infections when the fungus is resistant to fluconazole (another antifungal medicine),
- serious fungal infections caused by *Scedosporium sp*. or *Fusarium sp*. (two different species of fungi).

Voriconazole Aristo is intended for:
- patients with worsening, possibly life-threatening, fungal infections.
- prevention of fungal infections in high risk bone marrow transplant recipients.

This product should only be taken under the supervision of a doctor.

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

Do not take Voriconazole Aristo
If you are allergic to voriconazole or any of the other ingredients of this medicine (listed in section 6).

It is very important that you inform your doctor or pharmacist if you are taking or have taken any other medicines, even those that are obtained without a prescription, or herbal medicines.

The medicines in the following list must not be taken during your course of Voriconazole Aristo treatment:
- Terfenadine (used for allergy)
- Astemizole (used for allergy)

- Cisapride (used for stomach problems)
- Pimozide (used for treating mental illness)
- Quinidine (used for irregular heart beat)
- Ivabradine (used for symptoms of chronic heart failure)
- Rifampicin (used for treating tuberculosis)
- Efavirenz (used for treating HIV) in doses of 400 mg and above once daily
- Carbamazepine (used to treat seizures)
- Phenobarbital (used for severe insomnia and seizures)
- Ergot alkaloids (e.g., ergotamine, dihydroergotamine; used for migraine)
- Sirolimus (used in transplant patients)
- Ritonavir (used for treating HIV) in doses of 400mg and more twice daily
- St. John's Wort (herbal supplement)
- Naloxegol (used to treat constipation specifically caused by pain medicines, called opioids, (e.g., morphine, oxycodone, fentanyl, tramadol, codeine))
- Tolvaptan (used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline in patients with polycystic kidney disease)
- Lurasidone (used to treat depression)
- Finerenone (used to treat chronic kidney disease)
- Venetoclax (used to treat patients with chronic lymphocytic leukaemia-CLL)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Voriconazole Aristo if:
- you have had an allergic reaction to other azoles.
- you are suffering from, or have ever suffered from liver disease. If you have liver disease, your doctor may prescribe a lower dose of Voriconazole Aristo. Your doctor should also monitor your liver function while you are being treated with Voriconazole Aristo by doing blood tests.
- you are known to have cardiomyopathy, irregular heart beat, slow heart rate or an abnormality of electrocardiogram (ECG) called 'long QTc syndrome'.

You should avoid any sunlight and sun exposure while being treated. It is important to cover sun exposed areas of skin and use sunscreen with high sun protection factor (SPF), as an increased sensitivity of skin to the sun's UV rays can occur. This may be further increased by other medicines that sensitise the skin to sunlight, like methotrexate. These precautions are also applicable to children.

While being treated with Voriconazole Aristo:
- tell your doctor immediately if you develop
  - sunburn
  - severe skin rash or blisters
  - bone pain.

If you develop skin disorders as described above, your doctor may refer you to a dermatologist, who after consultation may decide that it is important for you to be seen on a regular basis. There is a small chance that skin cancer could develop with long-term use of Voriconazole Aristo**.**

If you develop signs of `adrenal insufficiency´ where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol which may lead to symptoms such as: chronic or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain, please tell your doctor.

If you develop signs of ´Cushing´s syndrome´ where the body produces too much of the hormone cortisol which may lead to symptoms such as: weight gain, fatty hump between the shoulders, a rounded face, darkening of the skin on the stomach, thighs, breasts, and arms, thinning skin, bruising easily, high blood sugar, excessive hair growth, excessive sweating, please tell your doctor.

Your doctor should monitor the function of your liver and kidneys by doing blood tests.

Children and adolescents

Voriconazole Aristo should not be given to children younger than 2 years of age.

Other medicines and Voriconazole Aristo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those that are obtained without a prescription.

Some medicines, when taken at the same time as Voriconazole Aristo, may affect the way Voriconazole Aristo works or Voriconazole Aristo may affect the way they work.

Tell your doctor if you are taking the following medicine, as treatment with Voriconazole Aristo at the same time should be avoided if possible:
- Ritonavir (used for treating HIV) in doses of 100 mg twice daily
- Glasdegib (used for treating cancer) – if you need to use both drugs your doctor will monitor your heart rhythm frequently

Tell your doctor if you are taking either of the following medicines, as treatment with Voriconazole Aristo at the same time should be avoided if possible, and a dose adjustment of voriconazole may be required:
- Rifabutin (used for treating tuberculosis). If you are already being treated with rifabutin your blood counts and side effects to rifabutin will need to be monitored.
- Phenytoin (used to treat epilepsy). If you are already being treated with phenytoin your blood concentration of phenytoin will need to be monitored during your treatment with Voriconazole Aristo and your dose may be adjusted.

Tell your doctor if you are taking any of the following medicines, as a dose adjustment or monitoring may be required to check that the medicines and/ or Voriconazole Aristo are still having the desired effect:
- Warfarin and other anticoagulants (e.g., phenprocoumon, acenocoumarol; used to slow down clotting of the blood)
- Ciclosporin (used in transplant patients)
- Tacrolimus (used in transplant patients)
- Sulphonylureas (e.g., tolbutamide, glipizide, and glyburide) (used for diabetes)
- Statins (e.g., atorvastatin, simvastatin) (used for lowering cholesterol)
- Benzodiazepines (e.g midazolam, triazolam) (used for severe insomnia and stress)
- Omeprazole (used for treating ulcers)
- Oral contraceptives (if you take Voriconazole Aristo whilst using oral contraceptives, you may get side effects such as nausea and menstrual disorders)
- Vinca alkaloids (e.g., vincristine and vinblastine) (used in treating cancer)
- Tyrosine kinase inhibitors (e.g., axitinib, bosutinib, cabozantinib, ceritinib, cobimetinib, dabrafenib, dasatinib, nilotinib, sunitinib, ibrutinib, ribociclib) (used for treating cancer)
- Tretinoin (used to treat leukaemia)
- Indinavir and other HIV protease inhibitors (used for treating HIV)
- Non-nucleoside reverse transcriptase inhibitors (e.g., efavirenz, delavirdine, nevirapine) (used for treating HIV) (some doses of efavirenz can NOT be taken at the same time as Voriconazole Aristo)
- Methadone (used to treat heroin addiction)
- Alfentanil and fentanyl and other short-acting opiates such as sufentanil (painkillers used for surgical procedures)
- Oxycodone and other long-acting opiates such as hydrocodone (used for moderate to severe pain)
- Non-steroidal anti-inflammatory drugs (e.g., ibuprofen, diclofenac) (used for treating pain and inflammation)
- Fluconazole (used for fungal infections)
- Everolimus (used for treating advanced kidney cancer and in transplant patients)
- Letermovir (used for preventing cytomegalovirus (CMV) disease after bone marrow transplant)
- Ivacaftor: used to treat cystic fibrosis
- Flucloxacillin (antibiotic used against bacterial infections)

Pregnancy and breast-feeding

Voriconazole Aristo must not be taken during pregnancy, unless indicated by your doctor. Effective contraception must be used in women of childbearing potential. Contact your doctor immediately if you become pregnant while taking Voriconazole Aristo.

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.

Driving and using machines
Voriconazole Aristo may cause blurring of vision or uncomfortable sensitivity to light. While affected, do not drive or operate any tools or machines. Contact your doctor if you experience this.

Voriconazole Aristo contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Voriconazole Aristo.

Voriconazole Aristo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially `sodium-free´.

3. How to take Voriconazole Aristo

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

Your doctor will determine your dose depending on your weight and the type of infection you have.

The recommended dose for adults (including elderly patients) is as follows:

		Tablets	
		Patients 40 kg and above	Patients less than 40 kg
Dose for the first 24 hours (Loading dose)		400 mg every 12 hours for the first 24 hours	200 mg every 12 hours for the first 24 hours
Dose after the first 24 hours (Maintenance dose)		200 mg twice a day	100 mg twice a day

Depending on your response to treatment, your doctor may increase the daily dose to 300 mg twice a day.

The doctor may decide to decrease the dose if you have mild to moderate cirrhosis.

Use in children and adolescents

The recommended dose for children and teenagers is as follows:

	Tablets	
	Children aged 2 to less than 12 years and teenagers aged 12 to 14 years weighing less than 50 kg	Teenagers aged 12 to 14 years weighing 50 kg or more; and all teenagers older than 14
Dose for the first 24 hours (Loading dose)	Your treatment will be started as an infusion	400 mg every 12 hours for the first 24 hours
Dose after the first 24 hours (Maintenance dose)	9 mg/kg twice a day (a maximum dose of 350 mg twice daily)	200 mg twice a day

Depending on your response to treatment, your doctor may increase or decrease the daily dose.
Tablets must only be given if the child is able to swallow tablets.

Take your tablet at least one hour before, or one hour after a meal. Swallow the tablet whole with some water.

If you or your child are taking Voriconazole Aristo for prevention of fungal infections, your doctor may stop giving Voriconazole Aristo if you or your child develop treatment related side effects.

Voriconazole Aristo 100 mg film-coated tablets can be divided into equal doses.

If you take more Voriconazole Aristo than you should
If you take more tablets than prescribed (or if someone else takes your tablets) you must seek medical advice or go to the nearest hospital casualty department immediately. Take your box of Voriconazole Aristo tablets with you. You may experience abnormal intolerance to light as a result of taking more Voriconazole Aristo than you should.

If you forget to take Voriconazole Aristo
It is important to take your Voriconazole Aristo tablets regularly at the same time each day. If you forget to take one dose, take your next dose when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Voriconazole Aristo
It has been shown that taking all doses at the appropriate times may greatly increase the effectiveness of your medicine. Therefore unless your doctor instructs you to stop treatment, it is important to keep taking Voriconazole Aristo correctly, as described above.

Continue taking Voriconazole Aristo until your doctor tells you to stop. Do not stop treatment early because your infection may not be cured. Patients with a weakened immune system or those with difficult infections may require long-term treatment to prevent the infection from returning.

When Voriconazole Aristo treatment is stopped by your doctor you should not experience any effects.

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

4. Possible side effects

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

If any side effects occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Serious side effects – Stop taking Voriconazole Aristo and see a doctor immediately
- Rash
- Jaundice; Changes in blood tests of liver function
- Pancreatitis

Other side effects

Very common: may affect more than 1 in 10 people
- Visual impairment (change in vision including blurred vision, visual colour alterations, abnormal intolerance to visual perception of light, colour blindness, eye disorder, halo vision, night blindness, swinging vision, seeing sparks, visual aura, visual acuity reduced, visual brightness, loss of part of the usual field of vision, spots before the eyes)
- Fever
- Rash
- Nausea, vomiting, diarrhoea
- Headache
- Swelling of the extremities

- Stomach pains
- Breathing difficulties
- Elevated liver enzymes

Common: may affect up to 1 in 10 people
- Inflammation of the sinuses, inflammation of the gums, chills, weakness
- Low numbers of some types, including severe, of red (sometimes immune related) and/or white blood cells (sometimes with fever), low numbers of cells called platelets that help the blood to clot
- Low blood sugar, low blood potassium, low sodium in the blood
- Anxiety, depression, confusion, agitation, inability to sleep, hallucinations
- Seizures, tremors or uncontrolled muscle movements, tingling or abnormal skin sensations, increase in muscle tone, sleepiness, dizziness
- Bleeding in the eye
- Heart rhythm problems including very fast heartbeat, very slow heartbeat, fainting
- Low blood pressure, inflammation of a vein (which may be associated with the formation of a blood clot)
- Acute breathing difficulty, chest pain, swelling of the face (mouth, lips and around the eyes), fluid accumulation in the lungs
- Constipation, indigestion, inflammation of the lips
- Jaundice, inflammation of the liver and liver injury
- Skin rashes which may lead to severe blistering and peeling of the skin characterized by a flat, red area on the skin that is covered with small confluent bumps, redness of the skin
- Itchiness
- Hair loss
- Back pain
- Kidney failure, blood in the urine, changes in kidney function tests
- Sunburn or severe skin reaction following exposure to light or sun
- Skin cancer

Uncommon: may affect up to 1 in 100 people
- Flu-like symptoms, irritation and inflammation of the gastrointestinal tract, inflammation of the gastrointestinal tract causing antibiotic associated diarrhoea, inflammation of the lymphatic vessels
- Inflammation of the thin tissue that lines the inner wall of the abdomen and covers the abdominal organ
- Enlarged lymph glands (sometimes painful), failure of blood marrow, increased eosinophils
- Depressed function of the adrenal gland, underactive thyroid gland
- Abnormal brain function, Parkinson-like symptoms, nerve injury resulting in numbness, pain, tingling or burning in the hands or feet
- Problems with balance or coordination
- Swelling of the brain
- Double vision, serious conditions of the eye including: pain and inflammation of the eyes and eyelids, abnormal eye movement, damage to the optic nerve resulting in vision impairment, optic disc swelling
- Decreased sensitivity to touch
- Abnormal sense of taste
- Hearing difficulties, ringing in the ears, vertigo
- Inflammation of certain internal organs- pancreas and duodenum, swelling and inflammation of the tongue
- Enlarged liver, liver failure, gallbladder disease, gallstones
- Joint inflammation, inflammation of the veins under the skin (which may be associated with the formation of a blood clot)
- Inflammation of the kidney, proteins in the urine, damage to the kidney
- Very fast heart rate or skipped heartbeats, sometimes with erratic electrical impulses
- Abnormal electrocardiogram (ECG)
- Blood cholesterol increased, blood urea increased

- Allergic skin reactions (sometimes severe), including a life-threatening skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth, inflammation of the skin, hives, skin redness and irritation, red or purple discoloration of the skin which may be caused by low platelet count, eczema
- Infusion site reaction
- Allergic reaction or exaggerated immune response
- Inflammation of the tissue surrounding the bone

Rare: may affect up to 1 in 1000 people
- Overactive thyroid gland
- Deterioration of brain function that is a serious complication of liver disease
- Loss of most fibers in the optic nerve, clouding of the cornea, involuntary movement of the eye
- Bullous photosensitivity
- A disorder in which the body's immune system attacks part of the peripheral nervous system
- Heart rhythm or conduction problems (sometimes life threatening)
- Life threatening allergic reaction
- Disorder of blood clotting system
- Allergic skin reactions (sometimes severe), including rapid swelling (oedema) of the dermis, subcutaneous tissue, mucosa and submucosal tissues, itchy or sore patches of thick, red skin with silvery scales of skin, irritation of the skin and mucous membranes, life-threatening skin condition that causes large portions of the epidermis, the skin's outermost layer, to detach from the layers of skin below
- Small dry scaly skin patches, sometimes thick with spikes or 'horns'

Side effects with frequency not known:
- Freckles and pigmented spots

Other significant side effects whose frequency is not known, but should be reported to your doctor immediately:
- Red, scaly patches or ring-shaped skin lesions that may be a symptom of an autoimmune disease called cutaneous lupus erythematosus

As Voriconazole Aristo has been known to affect the liver and the kidneys, your doctor should monitor the function of your liver and kidneys by doing blood tests. Please advise your doctor if you have any stomach pains or if your stools have a different consistency.

There have been reports of skin cancer in patients treated with voriconazole for long periods of time.

Sunburn or severe skin reaction following exposure to light or sun was experienced more frequently in children. If you or your child develops skin disorders, your doctor may refer you to a dermatologist, who after consultation may decide that it is important for you or your child to be seen on a regular basis. Elevated liver enzymes were also observed more frequently in children.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Voriconazole 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 or blister after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Voriconazole Aristo 100 mg film-coated tablets contain

- The active substance is voriconazole.
  Each tablet contains 100 mg voriconazole.

- The other ingredients are: lactose monohydrate, partially pregelatinized starch, maize starch, croscarmellose sodium, povidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide, triacetin

What Voriconazole Aristo 100 mg film-coated tablets look like and contents of the pack

White to almost white, oblong, film-coated tablets with a score line on one side and an approx. size of 10 mm x 6 mm x 4.6 mm. The tablet can be divided into equal doses.

Voriconazole Aristo 100 mg film-coated tablets are available in blister packs of 2, 10, 14, 20, 28, 30, 50, 56 and 100 film-coated tablets.
Not all pack sizes may be marketed.

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