

- 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

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 eosinophil
- 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 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, sunburn or severe skin reaction following exposure to light or sun, 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

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:

- Skin cancer
- Inflammation of the tissue surrounding the bone
- Red, scaly patches or ring-shaped skin lesions that may be a symptom of an autoimmune disease called cutaneous lupus erythematosus

Reactions during the infusion have occurred uncommonly with Voriconazole (including flushing, fever, sweating, increased heart rate and shortness of breath). Your doctor may stop the infusion if this occurs.

As Voriconazole has been known to affect the liver and the kidney, your doctor should monitor the function of your liver and kidney 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.

If any of these side effects persist or are troublesome, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or, 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store Voriconazole

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 label. The expiry date refers to the last day of that month.

Once reconstituted, Voriconazole should be used immediately, but if necessary may be stored for up to 24 hours at 2 °C - 8 °C (in a refrigerator). Reconstituted Voriconazole needs to be diluted with a compatible infusion solution first before it is infused. (Please refer to the end of this leaflet for further information).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Voriconazole contains

- The active substance is voriconazole.
- Voriconazole is a white or almost white powder for solution for infusion presented in 30 ml clear glass vials.
- The other ingredient is Sulfobutylbetadex sodium (see section 2, Voriconazole 200 mg powder for solution for infusion contains cyclodextrin and sodium).

Each vial contains 200 mg voriconazole, equivalent to a 10 mg/ml solution when reconstituted as directed by your hospital pharmacist or nurse (see the information at the end of this leaflet).

What Voriconazole looks like and contents of the pack

Voriconazole is presented in single use 30 ml Type I clear glass vial with a 20 mm grey colour chlorobutyl rubber stopper and blue colour aluminium-plastic overseal.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

AFT Pharma UK Limited

Olympia House,

Unit 13 2nd Floor, Armitage Road,

London, NW11 8RQ

England

Manufacturer:

Quercus Labo

Wijmenstraat 21P

9030 Mariakerke,

Belgium

This leaflet was last revised in June 2025.

The following information is intended for medical or healthcare professionals only:

Reconstitution and Dilution information

- Voriconazole powder for solution for infusion needs to first be reconstituted with either 19 ml of Water for Injections or 19 ml of 9 mg/ml (0.9%) Sodium Chloride for Infusion to obtain an extractable volume of 20 ml of clear concentrate containing 10 mg/ml voriconazole.
- Discard the Voriconazole vial if the vacuum does not pull the diluent into the vial.
- It is recommended that a standard 20 ml (non-automated) syringe be used to ensure that the exact amount (19.0 ml) of Water for Injections or of 9 mg/ml (0.9%) Sodium Chloride for Infusion is dispensed.
- The required volume of the reconstituted concentrate is then added to a recommended compatible infusion solution listed below to obtain a final Voriconazole solution containing 0.5 to 5 mg/ml of voriconazole.
- It is recommended that Voriconazole is administered at a maximum rate of 3 mg/kg per hour over 1 to 3 hours.
- This medicinal product is for single use only and any unused solution should be discarded and only clear solutions without particles should be used.
- Not for administration as a bolus injection.
- For storage information, please refer to Section 5 ‘How to store Voriconazole’.

Required Volumes of 10 mg/ml Voriconazole Concentrate

Body Weight (kg)	Volume of Voriconazole Concentrate (10 mg/ml) required for:				
	3 mg/kg dose (number of vials)	4 mg/kg dose (number of vials)	6 mg/kg dose (number of vials)	8 mg/kg dose (number of vials)	9 mg/kg dose (number of vials)
10	-	4.0 ml (1)	-	8.0 ml (1)	9.0 ml (1)
15	-	6.0 ml (1)	-	12.0 ml (1)	13.5 ml (1)
20	-	8.0 ml (1)	-	16.0 ml (1)	18.0 ml (1)
25	-	10.0 ml (1)	-	20.0 ml (1)	22.5 ml (2)
30	9.0 ml (1)	12.0 ml (1)	18.0 ml (1)	24.0 ml (2)	27.0 ml (2)
35	10.5 ml (1)	14.0 ml(1)	21.0 ml (2)	28.0 ml (2)	31.5 ml (2)
40	12.0 ml (1)	16.0 ml (1)	24.0 ml (2)	32.0 ml (2)	36.0 ml (2)
45	13.5 ml (1)	18.0 ml (1)	27.0 ml (2)	36.0 ml (2)	40.5 ml (3)
50	15.0 ml (1)	20.0 ml (1)	30.0 ml (2)	40.0 ml (2)	45.0 ml (3)
55	16.5 ml (1)	22.0 ml (2)	33.0 ml (2)	44.0 ml (3)	49.5 ml (3)
60	18.0 ml (1)	24.0 ml (2)	36.0 ml (2)	48.0 ml (3)	54.0 ml (3)
65	19.5 ml (1)	26.0 ml (2)	39.0 ml (2)	52.0 ml (3)	58.5 ml (3)
70	21.0 ml (2)	28.0 ml (2)	42.0 ml (3)	-	-
75	22.5 ml (2)	30.0 ml (2)	45.0 ml (3)	-	-
80	24.0 ml (2)	32.0 ml (2)	48.0 ml (3)	-	-
85	25.5 ml (2)	34.0 ml (2)	51.0 ml (3)	-	-
90	27.0 ml (2)	36.0 ml (2)	54.0 ml (3)	-	-
95	28.5 ml (2)	38.0 ml (2)	57.0 ml (3)	-	-
100	30.0 ml (2)	40.0 ml (2)	60.0 ml (3)	-	-

Voriconazole is a single dose unpreserved sterile lyophile. Therefore, from a microbiological point of view, the reconstituted solution must be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Compatible Infusion Solutions:

The reconstituted solution can be diluted with:

Sodium Chloride 9 mg/ml (0.9%) Solution for Injection

Compound Sodium Lactate Intravenous Infusion

5% Glucose and Lactated Ringer's Intravenous Infusion

5% Glucose and 0.45% Sodium Chloride Intravenous Infusion

5% Glucose Intravenous Infusion

5% Glucose in 20 mEq Potassium Chloride Intravenous Infusion

0.45% Sodium Chloride Intravenous Infusion

5% Glucose and 0.9% Sodium Chloride Intravenous Infusion

The compatibility of Voriconazole with diluents other than listed above (or listed below under ‘Incompatibilities’) is unknown.

Incompatibilities:

Voriconazole must not be infused into the same line or cannula concomitantly with other drug infusions, including parenteral nutrition (e.g., Aminofusin 10% Plus).

Infusions of blood products must not occur simultaneously with Voriconazole.

Infusion of total parenteral nutrition can occur simultaneously with Voriconazole but not in the same line or cannula.

Voriconazole must not be diluted with 4.2% Sodium Bicarbonate Infusion.