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 UK & Ireland Network Department	Length: 600 mm	Colours Used: <span style="border: 1px solid black; padding: 2px;">Template</span> <span style="border: 1px solid black; padding: 2px; background-color: #008000; color: white;">PANTONE GREEN C</span>	
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SKU (s): 7530363043 7530334043 7530335043	Perforated: No	Fonts: Univers Next Pro, Myriad Pro.	Smallest Font-Size: 12 pt (excluding codes)
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## Vanquoral 10 mg, 25 mg, 50 mg, 100 mg Capsules, soft ciclosporin

### Package leaflet: Information for the patient

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

## 1 What Vanquoral is and what it is used for

### What Vanquoral is

The name of your medicine is Vanquoral. It contains the active substance ciclosporin. This belongs to a group of medicines known as immunosuppressive agents. These medicines are used to lower the body's immune reactions.

### What Vanquoral is used for and how Vanquoral works

- **If you have had an organ transplant, bone marrow and stem cell transplantation**, the function of Vanquoral is to control your body's immune system. Vanquoral prevents rejection of transplanted organs by blocking the development of certain cells which would normally attack the transplanted tissue.
- **If you have an autoimmune disease**, in which your body's immune response attacks your body's own cells, Vanquoral stops this immune reaction. Such diseases include eye problems which threaten your vision (endogenous uveitis, including Behçet's uveitis), severe cases of certain skin diseases (atopic dermatitis, or eczema and psoriasis), severe rheumatoid arthritis and a kidney disease called nephrotic syndrome.

## 2 What you need to know before you take Vanquoral

If you are taking Vanquoral following a transplant it will only be prescribed for you by a doctor with experience in transplants and/or autoimmune diseases.

The advice in this leaflet may vary depending on whether you are taking the medicine for a transplant or for an autoimmune disease.

Follow all your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

### Do not take Vanquoral

- if you are allergic to ciclosporin or any of the other ingredients of this medicine (listed in section 6).
- with products containing *Hypericum perforatum* (St John's Wort).
- with products containing dabigatran etexilate (used to avoid blood clots after surgery) or bosentan and aliskiren (used to reduce high blood pressure).

Do not take Vanquoral and tell your doctor if the above applies to you. If you are not sure, talk to your doctor before taking Vanquoral.

### Warnings and precautions

#### Talk to your doctor or pharmacist before taking Vanquoral.

Before and during treatment with Vanquoral tell your doctor straight away

- if you have any signs of infection, such as fever or a sore throat. Vanquoral suppresses the immune system and may also affect your body's ability to fight against infection.
- if you have liver problems.
- if you have kidney problems. Your doctor will carry out regular blood tests and may change your dose if necessary.
- if you develop high blood pressure. Your doctor will check your blood pressure regularly and may give you a medicine to lower blood pressure if necessary.
- if you have low levels of magnesium in your body. Your doctor may give you magnesium supplements to take, especially just after your operation if you have had a transplant.
- if you have high levels of potassium in your blood.
- if you have gout.
- if you need to have a vaccination.

If any of the above applies to you before or during treatment with Vanquoral, tell your doctor straight away.

### Sunlight and sun protection

Vanquoral suppresses your immune system. This increases your risk of developing cancers, particularly of the skin and lymphoid system. You should limit your exposure to sunlight and UV light by:

- Wearing appropriate protective clothing.
- Often applying a sunscreen with a high protection factor.

### Monitoring during your treatment with Vanquoral

Your doctor will check:

- the levels of ciclosporin in your blood, especially if you have had a transplant,
- your blood pressure before the start of your treatment and regularly during treatment,
- how well your liver and kidneys are working,
- your blood lipids (fats).

If you have any questions about how Vanquoral works or why this medicine has been prescribed for you, ask your doctor.

**In addition if you are taking Vanquoral for a non-transplant disease** (intermediary or posterior uveitis and Behçet's uveitis, atopic dermatitis, severe rheumatoid arthritis or nephrotic syndrome), do not take Vanquoral:

- if you have kidney problems (except for nephrotic syndrome).
- if you have an infection which is not under control with medication.
- if you have any type of cancer.
- if you have high blood pressure (hypertension) which is not under control with medication. If you get high blood pressure during treatment and it cannot be controlled, Vanquoral should be stopped by your doctor.

Do not take Vanquoral if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Vanquoral.

If you are being treated for Behçet's uveitis, your doctor will monitor you particularly carefully if you have neurological symptoms (for example: increased forgetfulness, personality changes noticed over time, psychiatric or mood disorders, burning sensation in limbs, decreased sensation in limbs, tingling sensation in limbs, weakness of limbs, walking disturbances, headache with or without nausea and vomiting, vision disturbances including restricted movement of eyeball).

Your doctor will closely monitor you if you are elderly and are being treated for psoriasis or atopic dermatitis. If you have been prescribed Vanquoral to treat your psoriasis or atopic dermatitis, you must not be exposed to any UVB-rays or phototherapy during treatment.

### Children and adolescents

Vanquoral should not be given to children for a non-transplant disease, except for treatment of nephrotic syndrome.

### Elderly population (65 years of age and older)

There is limited experience with Vanquoral in elderly patients. Your doctor should monitor how well your kidneys work. If you are over 65 and have psoriasis or atopic dermatitis, you should only be treated with Vanquoral if your condition is particularly severe.

### Other medicines and Vanquoral

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

In particular tell your doctor or pharmacist if you are taking any of the following medicines before or during Vanquoral treatment:

- Medicines that may affect your potassium levels. These include medicines which contain potassium, potassium supplements, water tablets (diuretics) called potassium-sparing diuretics and some medicines which lower your blood pressure.
- Methotrexate. This is used to treat tumours, severe psoriasis and severe rheumatoid arthritis.
- Medicines which may increase or decrease the level of ciclosporin (the active substance of Vanquoral) in your blood. Your doctor might check the level of ciclosporin in your blood when starting or stopping treatment with other medicines.
  - o Medicines which may increase the level of ciclosporin in your blood include: antibiotics (such as erythromycin or azithromycin), anti-fungals (voriconazole, itraconazole), medicines used for heart problems or high blood pressure (diltiazem, nicardipine, verapamil, amiodarone), metoclopramide (used to stop sickness), oral contraceptives, danazol (used to treat menstrual problems), medicines used to treat gout (allopurinol), cholic acid and derivatives (used to treat gallstones), protease inhibitors used to treat HIV, imatinib (used to treat leukaemia or tumours), colchicine, telaprevir (used to treat hepatitis C), cannabidiol (uses amongst others include treatment of seizures).
  - o Medicines which may decrease the level of ciclosporin in your blood include: barbiturates (used to help you to sleep), some anti-convulsant medicines (such as carbamazepine or phenytoin), octreotide (used to treat acromegaly or neuroendocrine tumours in the gut), anti-bacterial medicines used to treat tuberculosis, orlistat (used to help weight loss), herbal medicines containing St. John's wort, ticlopidine (used after a stroke), certain medicines which lower blood pressure (bosentan), and terbinafine (an anti-fungal medicine used to treat infections of the toes and nails)..
- Medicines which may affect your kidneys. These include: anti-bacterial medicines (gentamycin, tobramycin, ciprofloxacin), anti-fungal medicines which contain amphotericin B, medicines used for urinary tract infections which contain trimethoprim,

medicines for cancer which contain melphalan, medicines used to lower the amount of acid in your stomach (acid secretion inhibitors of the H2-receptor antagonist type), tacrolimus, pain killers (non-steroid anti-inflammatory medicines such as diclofenac), fibric acid medicines (used to lower the amount of fat in the blood).

- Nifedipine. This is used to treat high blood pressure and heart pain. You might get swollen gums that might grow over your teeth if you are taking nifedipine during your treatment with ciclosporin.
- Digoxin (used to treat heart problems), medicines which lower cholesterol (HMG-CoA reductase inhibitors also called statins), prednisolone, etoposide (used to treat cancer), repaglinide (oral anti-diabetic medicine), immunosuppressives (everolimus, sirolimus), ambrisentan and specific anti-cancer medicines called anthracyclines (such as doxorubicin).
- Mycophenolate sodium or mycophenolate mofetil (an immunosuppressant) and eltrombopag (used to treat bleeding disorders)

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Vanquoral.

### Hepatitis C

Tell your doctor if you have hepatitis C. Your liver function may change with treatment of hepatitis C and this may affect the levels of ciclosporin in your blood. Your doctor may need to closely monitor ciclosporin blood levels and make adjustments to the dose of Vanquoral after you start treatment for hepatitis C.

### Vanquoral with food and drink

Do not take Vanquoral with grapefruit or grapefruit juice. This is because these can affect how Vanquoral works.

### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

- Tell your doctor if you are pregnant or intend to become pregnant. Experience with Vanquoral in pregnancy is limited. In general, Vanquoral should not be taken during pregnancy. If it is necessary for you to take this medicine, your doctor will discuss with you the benefits and potential risks of taking it during pregnancy.
- Tell your doctor if you are breast-feeding. Breast-feeding is not recommended during treatment with Vanquoral. This is because ciclosporin, the active substance, passes into breast milk. This may affect your baby.

### Driving and using machines

You may feel sleepy, disoriented, or have blurred vision after taking Vanquoral. Be careful driving or operating machinery while you are taking Vanquoral until you know how it affects you.

### Vanquoral contains ethanol

- 10 mg**  
This medicine contains 15.95 mg of alcohol (ethanol) in each capsule.
- 25 mg**  
This medicine contains 39.86 mg of alcohol (ethanol) in each capsule.
- 50 mg**  
This medicine contains 79.75 mg of alcohol (ethanol) in each capsule.
- 100 mg**  
This medicine contains 159.50 mg of alcohol (ethanol) in each capsule.

The amount in a 500 mg dose of this medicine (797.5 mg ethanol) is equivalent to less than 20 ml beer or 8 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

### Vanquoral contains sorbitol

- 10 mg**  
This medicine contains 2.93 mg sorbitol in each capsule.
- 25 mg**  
This medicine contains 4.92 mg sorbitol in each capsule.
- 50 mg**  
This medicine contains 11.03 mg sorbitol in each capsule.
- 100 mg**  
This medicine contains 19.06 mg sorbitol in each capsule.

**Vanquoral contains macrogolglycerol hydroxystearate**  
May cause stomach upset and diarrhoea.

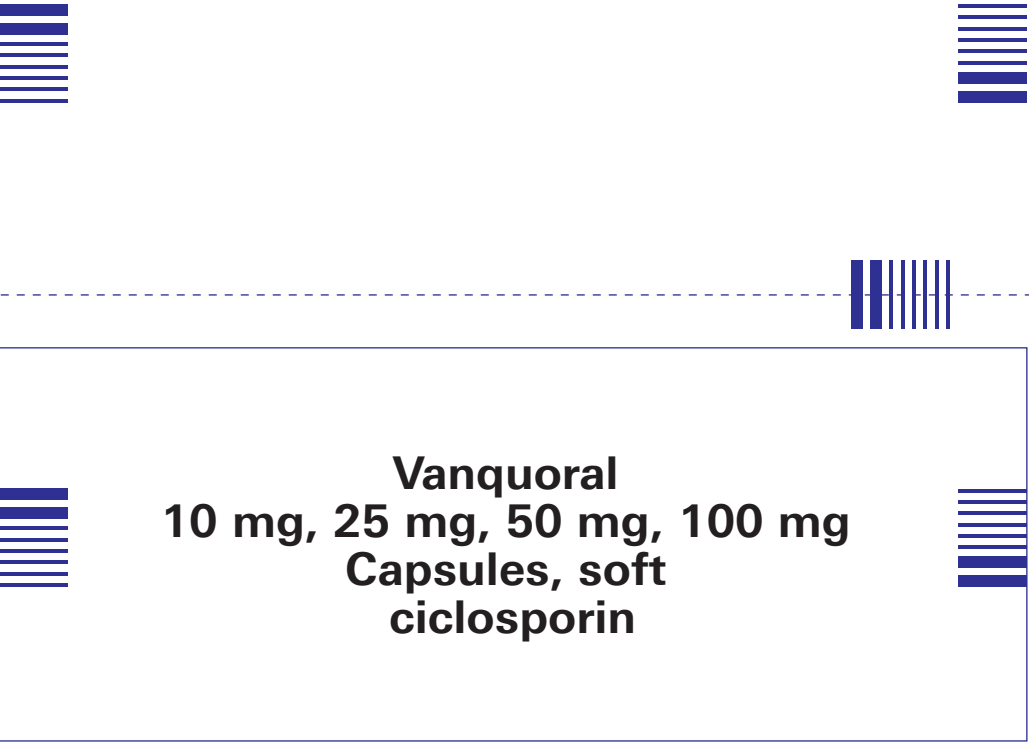
## 3 How to take Vanquoral

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Do not take more than the recommended dose.

The dose of this medicine will be carefully adjusted to your individual needs by your doctor. Too much of the medicine can affect your kidneys. You will have regular blood tests and visits to the hospital, especially after a transplant. This will give you the chance to talk to your doctor about your treatment and talk about any problems you may be having.

### How much Vanquoral to take

Your doctor will work out the correct dose of Vanquoral for you. This depends on your body weight and what you are taking the medicine for. Your doctor will also tell you how often to take your medicine.



**Vanquoral**  
**10 mg, 25 mg, 50 mg, 100 mg**  
**Capsules, soft**  
**ciclosporin**

- **In adults:**
    - Organ, bone marrow and stem cell transplantation**
      - o The total dose each day is usually between 2 mg and 15 mg per kilogram body weight. This is divided in two doses.
      - o Usually, higher doses are used before and just after your transplant. Lower doses are used once your transplanted organ or bone marrow has stabilised.
      - o Your doctor will adjust your dose to one that is ideal for you. To do this, your doctor may need to do some blood tests.
    - Endogenous uveitis**
      - o The total dose each day is usually between 5 mg and 7 mg per kilogram body weight. This is divided in two doses.
    - Nephrotic syndrome**
      - o The total dose each day for adults is usually 5 mg per kilogram body weight. This is divided in two doses. In patients with kidney problems, the first dose taken each day should not be more than 2.5 mg per kilogram body weight.
    - Severe rheumatoid arthritis**
      - o The total dose each day is usually between 3 mg per kilogram of your body weight and 5 mg per kilogram body weight. This is divided in two doses.
    - Psoriasis and atopic dermatitis**
      - o The total dose each day is usually between 2.5 mg per kilogram of your body weight and 5 mg per kilogram body weight. This is divided in two doses.
  - **In children:**
    - Nephrotic syndrome**
      - o The total dose each day for children is usually 6 mg per kilogram body weight. This is divided in two doses. In patients with kidney problems, the first dose taken each day should not be more than 2.5 mg per kilogram body weight.
- Follow your doctor's instructions exactly and never change the dose yourself, even if you feel well.

#### How to take Vanquoral

Your daily doses should always be taken in 2 divided doses. Remove the capsules from the blister. Swallow the capsules whole with water.

#### How long to take Vanquoral

Your doctor will tell you how long you need to take Vanquoral for. This depends on whether you are taking it after a transplant or for the treatment of a severe skin condition, rheumatoid arthritis, uveitis or nephrotic syndrome. For severe rash, the treatment usually lasts for 8 weeks.

Keep taking Vanquoral for as long as your doctor tells you. If you have questions about how long to take Vanquoral, talk to your doctor or your pharmacist.

#### If you take more Vanquoral than you should

If you accidentally take too much of your medicine, tell your doctor immediately or go to your nearest hospital emergency unit. You may need medical attention.

#### If you forget to take Vanquoral

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Then go on as before. Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Vanquoral

Do not stop taking Vanquoral unless your doctor tells you to. Keep taking Vanquoral even if you feel well. Stopping your treatment with Vanquoral may increase the risk of your transplanted organ being rejected.

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.

#### Some side effects could be serious

**Tell your doctor straight away** if you notice any of the following serious side effects:

- Like other medicines that act on the immune system, ciclosporin may influence your body's ability to fight against infection and may cause tumours or other cancers, particularly of the skin. Signs of infection might be fever or sore throat.
- Changes in your sight, loss of coordination, being clumsy, memory loss, difficulty speaking or understanding what others say, and muscle weakness. These might be signs of an infection of the brain called progressive multifocal leukoencephalopathy.
- Brain problems with signs such as seizures, confusion, feeling disorientated, being less responsive, personality changes, feeling agitated, sleeplessness, changes to your sight, blindness, coma, paralysis of part or all of the body, stiff neck, loss of coordination with or without unusual speech or eye movements.
- Swelling at the back of the eye. This may be associated with blurred vision. It may also affect your sight because of the higher pressure inside your head (benign intracranial hypertension).
- Liver problems and damage with or without yellow skin and eyes, nausea, loss of appetite and dark urine.
- Kidney problems which may greatly reduce the amount of urine you produce.
- Low level of red blood cells or platelets. The signs include pale skin, feeling tired, being breathless, having dark urine (this is a sign of the breakdown of red blood cells), bruising or bleeding with no obvious reasons, feeling confused, feeling disorientated, being less alert and having kidney problems.

#### Other side effects include:

#### Very common side effects:

- Kidney problems.
- High blood pressure.
- Headache.
- Shaking of your body which you cannot control.
- Excessive growth of body and facial hair.
- High level of lipids in your blood.

If any of these affects you severely, tell your doctor.

#### Common side effects:

- Fits (seizures).
- Liver problems.
- High level of sugar in your blood.
- Tiredness.
- Loss of appetite.
- Nausea (feeling sick), vomiting, abdominal discomfort/pain, diarrhoea.
- Excessive hair growth.
- Acne, hot flushes.
- Fever.
- Low level of white blood cells.
- Feeling numb or tingling.
- Pain in your muscles, muscle spasm.
- Stomach ulcer.
- Gum tissue overgrowing and covering your teeth.

- High level of uric acid or potassium in your blood, low levels of magnesium in your blood.

If any of these affects you severely, tell your doctor.

#### Uncommon side effects:

- Symptoms of brain disorders including sudden fits, mental confusion, sleeplessness, disorientation, disturbance of vision, unconsciousness, sense of weakness in the limbs, impaired movements.
- Rash.
- General swelling.
- Weight gain.
- Low level of red blood cells, low level of platelets in your blood which could increase the risk of bleeding.

If any of these affects you severely, **tell your doctor**.

#### Rare side effects:

- Nerve problems with numbness or tingling in fingers and toes.
- Inflammation of the pancreas with severe upper stomach pain.
- Muscle weakness, loss of muscle strength, pain in muscles of the legs or hands or anywhere in the body.
- Destruction of red blood cells, involving kidney problems with symptoms such as swelling of the face, stomach, hands and/or feet, decreased urination, breathing difficulty, chest pain, fits, unconsciousness.
- Changes in menstrual cycle, breast enlargement in men.

If any of these affects you severely, tell your doctor.

#### Very rare side effects:

- Swelling at the back of the eye which may be associated with an increase in pressure inside the head and eyesight disturbances.

If this affects you severely, tell your doctor.

#### Not known:

- frequency cannot be estimated from the available data.
- Serious liver problems both with and without yellowing of the eyes or skin, nausea (feeling sick), loss of appetite, dark coloured urine, swelling of the face, feet, hands and/or the whole body.
- Bleeding underneath the skin or purple skin patches, sudden bleeding with no apparent cause.
- Migraine or severe headache often with feeling and being sick (nausea, vomiting) and being sensitive to light.
- Pain in legs and feet.
- Hearing impairment

If any of these affects you severely, tell your doctor.

#### Additional side effects in children and adolescents

There are no additional side effects to be expected in children and adolescents compared to adults.

#### 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 at: [www.mhra.gov.uk/yellowcard](http://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 Vanquoral

#### 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 box and blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Do not freeze.

Store in the original package in order to protect from light and moisture.

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 Vanquoral contains

- The active substance is ciclosporin.
- **10 mg**
- Each soft capsule contains 10 mg ciclosporin.
- **25 mg**
- Each soft capsule contains 25 mg ciclosporin.
- **50 mg**
- Each soft capsule contains 50 mg ciclosporin.
- **100 mg**
- Each soft capsule contains 100 mg ciclosporin.
- The other ingredients in the capsule fill are macrogolglycerol hydroxystearate; glycerol monolinoleate, diethylene glycol monoethyl ether; ethanol, anhydrous; D,L- $\alpha$ -tocopherol. The other ingredients in the capsule shell are
- **10 mg**
- gelatin; glycerol (85 per cent); sorbitol, liquid (non-crystallising) (E420); glycine; titanium dioxide (E171); paraffin, light liquid.

#### 25 mg + 50 mg

gelatin; glycerol (85 per cent); sorbitol, liquid (non-crystallising) (E420); glycine; titanium dioxide (E171); iron oxide yellow (E172); paraffin, light liquid.

#### 100 mg

gelatin; glycerol (85 per cent); sorbitol, liquid (non-crystallising) (E420); glycine; titanium dioxide (E171); iron oxide brown (E172); paraffin, light liquid.

#### What Vanquoral looks like and contents of the pack

**10 mg**  
Opaque white to off-white soft gelatin capsules containing colourless to slightly yellowish oily liquid, approximate size of 9.0 x 5.5 mm.

#### 25 mg

Opaque yellow soft gelatin capsules containing colourless to slightly yellowish oily liquid, with printing the IVAX "hourglass" logo "25", approximate size of 12.2 x 7.6 mm.

#### 50 mg

Opaque ochre-yellow soft gelatin capsules containing colourless to slightly yellowish oily liquid, with printing the IVAX "hourglass" logo "50", approximate size of 20.7 x 7.8 mm.

#### 100 mg

Opaque brown soft gelatin capsules containing colourless to slightly yellowish oily liquid, with printing the IVAX "hourglass" logo "100", approximate size of 24.7 x 9.9 mm.

#### 10 mg + 25 mg + 50 mg

The capsules are available in pack sizes of 20, 30, 50, 50x1, 60, 90 and 100 in OPA/Alu/PVC – Aluminium blisters.

#### 100 mg

The capsules are available in pack sizes of 20, 30, 30x1, 50, 50x1, 60, 90 and 100 in OPA/Alu/PVC – Aluminium blisters.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

#### Manufacturer

Teva Czech Industries s.r.o., Ostravska 29, c.p. 305, 74770 Opava-Komarov, Czech Republic

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