Wilate is used to treat and prevent bleeding in patients with von Willebrand disease (VWD), which in fact is a family of related diseases.

Wilate is used to treat and prevent bleeding in patients with haemophilia A. This is a condition in which bleeding can go on for longer than expected. It is due to an inborn lack of FVIII in the blood.

Before you use Wilate

Do not use Wilate

- if you are allergic (hypersensitive) to human blood coagulation factor VII (VWF) or von Willebrand factor or any of the other ingredients of Wilate.

Take special care with Wilate

- Any medicine, such as Wilate, which is prepared from human blood (containing proteins) and which is injected into a vein (administered intravenously) can cause allergic reactions. Please pay attention to early signs of allergic reactions (hypersensitivity), such as hives, skin rash, tightness of the chest, swallowing, low blood pressure, or anaphylaxis (when any or all of the above symptoms develop rapidly and are serious).

If these symptoms occur, stop the injection immediately and contact your doctor.

- When medicines are made from human blood or plasma, certain measures are put in place to prevent infection being passed on to patients. These include careful selection of blood and plasma donors, a record of those at risk of infection being excluded, and the testing of each donation and pools of plasma for signs of infection. Moreover, all medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections. The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B (HBV) virus and hepatitis C (HCV) virus, and for the non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (infection of the baby) and for individuals whose immune system is depressed or who have some types of anaemia (e.g. sickle cell diseases). Inhibitors may increase the risk of suffering severe allergic reactions (anaphylactic shock). If you suffer an allergic reaction, you should stop using Wilate immediately and contact your doctor.

Important information about some of the ingredients of Wilate

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

- Even though uncommon, hypersensitivity or allergic reactions have been observed. These may include:
  - burning and stinging at the infusion site, chill, flushing, headache, hives (urticaria), muscle pain, rash, swelling, sweating, sudden swelling in various parts of the body (angioedema).
  - fever, chills.

If you suffer from any of the above-mentioned symptoms, please inform your doctor.

You should stop using Wilate and see your doctor immediately, if you experience symptoms of anaphylactic shock.

- difficulties to inhale
- swelling of face, tongue or throat (pharynx)

- On rare occasions, fever has been observed.

- in very rare cases, hypersensitivity may lead to a severe allergic reaction called anaphylaxis (when any or all of the above symptoms develop rapidly and are serious), which may include shock. In case of an anaphylactic shock, treatment using the current medical recommendations for shock is essential.

6. Further information

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before using Wilate.

Important information about some of the ingredients of Wilate

This medicinal product contains up to 2.55 mmol sodium (58.7 mg) per dose for 500 IU FVIII and VWF and up to 5.1 mmol sodium (117.3 mg) per dose for 1000 IU FVIII and VWF. To be taken into consideration if you are on a controlled sodium diet.

3. How to use Wilate

Wilate should be injected into a vein (administered intravenously) after appropriate consultation with the supplied solvent. Treatment should be started under medical control.

Dosage

Your doctor will advise you about your individual dosage and the frequency with which you should use Wilate. Always use Wilate exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you use more Wilate than you should

- Inhibitors may increase the risk of suffering severe allergic reactions (anaphylactic shock). If you suffer an allergic reaction, you should stop using Wilate immediately and contact your doctor.

If you forget to take Wilate

- Do not take a double dosage to make up for a forgotten dosage.

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

4. Possible side effects

Very rare:

- hives (urticaria), low blood pressure (hypotension), tiredness (fatigue), tachycardia (rapid heartbeat), feeling of pins and needles (tingling), vomiting, sweining, sudden swelling in various parts of the body (angioedema).

Rare:

- tightness of the chest, feeling of pins and needles (numbness), low blood pressure, or anaphylaxis (when any or all of the above symptoms develop rapidly and are serious).

Uncommon:

- strong headache
- swelling of the lips, tongue or throat

- nausea, vomiting

- severe allergic reaction (anaphylactic shock).

If you suffer from any of the above-mentioned symptoms, please inform your doctor.

- You should stop using Wilate and see your doctor immediately, if you experience symptoms of anaphylactic shock.

- you are a patient with brown clinical or laboratory risk factors, you have to be checked for early signs of thrombosis. Prevention of exacerbation of thrombotic events may be decided by your doctor, according to the current recommendations.

- patients with VWD (especially type 2 patients) may develop inhibitors (neutralizing antibodies) to VWF during the treatment with VWF in these very rare cases inhibitors can stop Wilate working properly.

In case your bleeding continues, your blood has to be tested for the presence of inhibitors.

Inhibitors may increase the risk of suffering severe allergic reactions (anaphylactic shock). If you suffer an allergic reaction, you should be tested for the presence of inhibitors.

Inhibitors may increase the risk of suffering severe allergic reactions (anaphylactic shock). If you suffer an allergic reaction, you should be tested for the presence of inhibitors.
The experience of treatment with Wilate in children less than 6 years of age is limited.

5. How to store Wilate

Keep out of the reach and sight of children.

Store powder and solvent vial in a refrigerator (2°C - 8°C).

Do not freeze.

Keep the vials in the outer carton to protect from light.

Do not use Wilate after the expiry date stated on the label.

Wilate can be stored at room temperature (max. +25°C) for 2 months.

In this case the shelf-life expires 2 months after the product has been taken out of the refrigerator for the first time. The new shelf-life has to be displayed on the outer carton by you.

The powder should be dissolved only directly before injection. The stability of the solution has been demonstrated for 12 hours at room temperature.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

6. Further information

What Wilate contains

- The active substances are human coagulation factor VIII and human von Willebrand factor
- The other ingredients are sodium chloride, glycyne, succrose, sodium citrate and calcium chloride. Solvent: water for injections with 0.1% Polysorbate 80

What Wilate looks like and contents of the pack

Freeze-dried powder: white or pale yellow powder or crumbly solid

Reconstituted solution: should be clear or slightly opalescent

Wilate is supplied as a powder and solvent for solution for injection. It comes in 2 pack sizes:

- Wilate 500, 500 IU FVIII and 500 IU VWF, powder and solvent for solution for injection, contains nominally 500 IU human coagulation factor VIII and 500 IU human von Willebrand factor per vial. The product contains approximately 100 IU/ml human coagulation factor VIII and 100 IU/ml human von Willebrand factor when reconstituted with 5 ml of Water for Injections (with 0.1% Polysorbate 80 Solvent)

- Wilate 1000, 1000 IU FVIII and 1000 IU VWF, powder and solvent for solution for injection, contains nominally 1000 IU human coagulation factor VIII and 1000 IU human von Willebrand factor per vial. The product contains approximately 100 IU/ml human coagulation factor VIII and 180 IU/ml human von Willebrand factor when reconstituted with 10 ml of Water for Injections with 0.1% Polysorbate 80 Solvent)

Content of the package

1 vial with freeze-dried powder
1 vial with solvent
1 equipment pack with the following medical devices:
1 disposable syringe
1 transfer set (Mix2Vial™)
1 infusion set
2 alcohol swabs

Marketing Authorisation Holder

Octapharma Limited
The Zenith Building
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Manchester M1 1AB
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For any further information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last approved in 11/2011.

This medicinal product is available in the Member States of the European Economic Area (EEA) including:

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Spain, United Kingdom: Wilate

Denmark: Winvetro

In case of an adverse reaction or if you are uncertain about what to do, please contact your doctor or pharmacist.