

Thrombotrol®-VF

Antithrombin III Concentrate (Human), for intravenous administration

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Thrombotrol®-VF. It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Thrombotrol®-VF against the benefits they expect it will have for you.

If you have any concerns about having this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What Thrombotrol®-VF is used for

This medicine is used to prevent blood clots in people who have an inherited deficiency of antithrombin III in the following circumstances:

- before surgery
- during pregnancy
- during childbirth.

It can also be used to treat blood clots in these patients.

This medicine belongs to a group of medicines called antithrombotic agents. It works by increasing antithrombin III levels and thereby preventing the formation of blood clots.

Some people have an inherited deficiency of antithrombin III and these people may be at risk of spontaneous thrombosis (blood clots) or pulmonary embolism (blood clot which stops blood circulating through the lungs). The risk of these conditions increases with age and in association with surgery, pregnancy and childbirth.

Thrombotrol®-VF contains a concentrated form of antithrombin III which is a protein normally present in the blood and prevents the formation of blood clots.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you are given Thrombotrol®-VF

When you must not have it

Do not have Thrombotrol®-VF if you have an allergy to:

- any medicine containing antithrombin III
- any of the ingredients listed at the end of this leaflet
- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Before you start to have it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant, are breast-feeding, or have any other medical conditions.

Your doctor can discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Thrombotrol®-VF.

About blood products

This product is made from human plasma. When products are made from human blood, it is possible that viruses or other substances could be present in the product and cause an illness. These could include different types of viral hepatitis, human immunodeficiency virus (HIV), or parvovirus B19 and theoretically the Creutzfeldt-Jakob Disease (CJD) agent. There could also be other infectious agents which may have not yet been discovered.

To reduce the risk of this happening precautions are taken when manufacturing this product. Strict controls are applied when selecting blood donors and donations. The product is specially treated to remove and kill certain viruses. This special treatment is considered effective against viruses known as enveloped viruses (such as HIV, hepatitis B and C) and the non-enveloped virus, hepatitis A. Effectiveness against the non-enveloped virus parvovirus B19 may be limited.

Despite these measures, the risk of contamination with viruses or other agents cannot be completely eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Note: The safety and effectiveness of Thrombotrol®-VF in children and elderly has not been established.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Thrombotrol®-VF may interfere with each other. These include:

- Heparin. Concurrent use of antithrombin III concentrates may enhance the anticoagulant effect of heparin.

Other medicines may be affected by Thrombotrol®-VF or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid while taking this medicine.

How to use Thrombotrol®-VF

Thrombotrol®-VF is only available from and given by your doctor. The dose calculated by your doctor is given by intravenous infusion (a slow injection into the vein). Ask your doctor if you have any questions about the way this medicine is administered.

While you are having Thrombotrol®-VF

Things you must do

If you are about to be started on any new medicine, remind your doctor that you are having Thrombotrol®-VF.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are having Thrombotrol®-VF.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Furthermore, individual patients may react differently to the same dose of the same medicine. This applies to Thrombotrol®-VF.

Unwanted effects associated with antithrombin III concentrates are not common.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- foul taste in mouth
- abdominal pain.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- hives
- fever
- bruises.

The above side effects include serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately:

- dizziness, light-headedness
- chest tightness
- shortness of breath.

The above list includes very serious side effects. You may need urgent medical attention.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

Storing Thrombotrol®-VF

Thrombotrol®-VF should be stored in a refrigerator (at 2°C to 8°C) and protected from light. Do not freeze. It should not be used after the expiry date has passed.

Further information

If you want further information about Thrombotrol®-VF and your treatment generally, consult your doctor.

Product description

What it looks like

Thrombotrol®-VF is available as a white powder contained in a glass vial. The product comes with a vial of Water for Injections for reconstitution, and a Mix2Vial™ filter transfer set.

Ingredients

Thrombotrol®-VF contains 1000 International Units (IU) of antithrombin III concentrate (human) as the active ingredient. It also contains:

- other plasma proteins
- sodium
- chloride
- citrate.

Manufacturer

Thrombotrol®-VF is manufactured in Australia by:

CSL Behring (Australia) Pty Ltd

ABN 48 160 734 761

189-209 Camp Road

Broadmeadows VIC 3047

Australia

Distributor

Australian Red Cross Blood Service

Date of most recent amendment

August 2014

Australian Register Number:

AUST R 66736

® Registered trademark of CSL Limited

™ Mix2Vial is a trademark of West

Pharmaceutical Services, Inc. or a subsidiary thereof