RECOMBINATE

(Antihaemophilic factor VIII)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about the RECOMBINATE. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks against the benefits for you by using RECOMBINATE.

It does not take the place of talking to your doctor or pharmacist. If you have any concerns about having this medicine, ask your doctor or pharmacist.

What RECOMBINATE is used for?

RECOMBINATE belongs to the group of medicines called blood coagulation factor VIII.

It is used for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). This preparation does not contain von Willebrand factor and is therefore not indicated in von Willebrand's disease.

RECOMBINATE is a recombinant-derived factor VIII, which has been successfully shown to correct factor VIII deficiency. Plasma derived factor VIII has also been used for the same purpose, but due to a possible transmission of blood-borne viral impurity in the product, it is now replaced by a recombinant derived factor VIII.

How does RECOMBINATE work?

Under a normal physiological condition, factor VIII is essential for blood clotting and maintenance of bleeding episode. Individuals with haemophilia A disease, a sex-linked hereditary disorder of blood coagulation, have a decreased factor VIII in their blood circulation. As a result of factor VIII deficiency, the individual with this disease may lead to a heavy bleeding into joints, muscles or internal organ, either spontaneously or resulted from an accidental or surgical trauma.

The property of RECOMBINATE is similar with that of plasma derived factor VIII. Thus, it works in the same way as factor VIII that is normally present in a healthy individual, a replacement therapy.

Before you are given the RECOMBINATE

RECOMBINATE should not be given to you if:

- you are allergic (hypersensitive) to mouse, hamster proteins or any other ingredients in this product.
- you have tendency of allergic reaction or hypersensitivity to any human derived protein injection. Some of the symptoms of an allergic reaction may include skin rash, swelling of the face, lips or tongue, which may cause difficulty swallowing or shortness of breath.
- the expiry date printed on the pack has passed.

You must tell your doctor if you:

- have any other illness
- are taking any prescription medicine or any other medicines purchased from a pharmacy, health food store or supermarket. Some medicines and RECOMBINATE may interfere with each other.

You must tell your doctor, if you are pregnant, planning to become pregnant or breast-feeding.

The use of RECOMBINATE during pregnancy is not recommended, due to insufficient information in supporting of such usages, because haemophilia is rare in female (haemophilia is male sex-linked hereditary congenital disorder). If there is a need to consider the use of this product during your pregnancy or breast feeding, your doctor will discuss the risks and benefit with you.

How RECOMBINATE is given

How much is given:

Your doctor will decide how much RECOMBINATE will be given to you, which depends on your need and condition. Each individual will receive a different dosage, which in itself may vary between doctor visits. The dose you receive will be based on:

a. body weight;
b. the amount of factor VIII your body is able to make;
c. how much, how often and which sites (knees, muscle, etc) of your body are bleeding;
d. whether your body may build up antibodies to this medicine. After a while your body may build up these antibodies, leading to a less effective treatment than the usual.

If you miss/forget your injection:

Proceed with the next administration immediately, and continue at regular intervals as advised by your doctor. Do not take a double dose to make up the forgotten dose.

Reconstitution - (Use aseptic technique)

1. Bring RECOMBINATE (dry concentrate) and Sterile Water for Injection, USP (diluent) to room temperature.
2. Remove caps from the concentrate and diluent vial.
3. Cleanse stoppers with germicidal solution and allow to dry prior to use.
4. Remove protective covering from one end of double-ended needle and insert exposed needle through the centre of diluent stopper.
5. Remove protective covering from other end of the double-ended needle. Invert diluent vial over the upright RECOMBINATE vial, then rapidly insert free end of the needle through the RECOMBINATE vial stopper at its centre. The vacuum in the vial will draw in the diluent.
6. Disconnect the two vials by removing the needle from the diluent vial stopper, then remove the needle from the RECOMBINATE vial. Swirl gently until all the material is dissolved. Be sure that the RECOMBINATE is completely dissolved, otherwise the active material will be removed by the filter needle.

Method of Administration (use aseptic technique):

RECOMBINATE is usually administered in the hospital. However, some individuals may be trained to use RCOMBINATE at home. It is administered by intravenous injection.

If you are injecting at home, take the dry medicine vial and the small vial of water out of the refrigerator and let them come to room temperature (15°C to 30°C). Visually examine the dry medicine vial and contents, and do not use if there is any sign of damage or discolouration. The dry medicine should appear off-white to faint yellow.

After cleaning the stoppers, use a plastic disposable syringe (not glass) and a double-ended needle to inject the water into the dry medicine, aiming the water against the wall of the dry medicine container. This will prevent foaming. Dissolve the medicine by swirling. Do not shake the container, as it contains a surfactant, polysorbate 80, which causes foaming upon shaking.

After preparation, the medicine should be used immediately or at least within 3 hours after it is prepared. Do not refrigerate after reconstitution. Please refer to the directions on the package or talk to your doctor.

Do not reuse syringes and needles. Place them in a puncture resistant disposable container, or otherwise dispose of them as directed by your doctor. Likewise, discard any unused solution as directed by your doctor.

Case of overdose

No symptoms of overdose with RECOMBINATE have been reported

While you are treated with RECOMBINATE

Discuss with your doctor the progress you have experienced after the treatment, especially during the first few days. As RECOMBINATE is given in a hospital, your healthcare professional will take records of the progress and unexpected reactions.

ADVERSE EFFECTS

Adverse effects from the use of RECOMBINATE are rare. However, if you suffer from any of the following symptoms, stop the infusion immediately and alert your doctor.

Seek medical attention immediately if any of the following side effects occur, as these may mean that you are having a severe allergic response to the medicine:

- fast or irregular breathing
- shortness of breath
- troubled breathing
- tightness in the chest and/or wheezing
- changes in facial skin colour
- puffiness or swelling of the eyelids or around the eyes or face
- skin rash
- dizziness
- abnormal sensation
- low blood pressure

- loss of consciousness
- hives
- itching

Also check with your doctor if any of the following less common or rare side effects occur:

- chills
- fever
- nausea
- tenderness
- swelling
- pain and skin discolouration at the injection site plus warmth or noticeable veins over affected area
- unusual lethargy or weakness
- chest tightness
- coughing
- short of breath
- low blood pressure
- trembling
- unusual bleeding or bruising
- fast heart beat
- bluish discolouration of the skin
- chest pain or discomfort

Other side effects may occur that usually do not need medical attention. These side effects are less common and may go away during treatment as your body adjusts to the medicine. However, please see your doctor if any of the following side effects continue:

- burning
- stinging
- dizziness or light-headedness
- headache
- nose-bleed
- swelling at the injection site
- dry mouth or bad taste
- redness of the face
- vomiting
- perspiration
- ear infection or hearing problems
- cold fingers and toes
- rash
- tingling or numbness of the hands or feet (pins and needles)

Please consult your doctor if you experience any of the unwanted effects as listed above.

Product descriptions

What RECOMBINATE looks like?

It is presented in a white to cream colour powder in a single dose glass vial accompanied by sterile water for injection in glass vial for reconstitution. The package also contains a double-ended needle and package insert.

What is in RECOMBINATE?

The active ingredient in RECOMBINATE is antihaemophilic factor [Recombinant Coagulation Factor VIII (rhc)], produced by recombinant technology. Three strengths, 250 IU, 500 IU, and 1000 IU of RECOMBINATE are commercially available.

The amounts of each component of the excipients in all strengths are the same. Thus, after reconstitution with 10 mL of Water for Injections each vial contains in maximum amounts: human Albumin (125 mg), Sodium Chloride (105 mg), Histidine (85 mg), Macrogol 3350 (15 mg), Calcium Chloride (7.3 mg), Polysorbate 80 (1.5 µg/IU).

How to store RECOMBINATE

RECOMBINATE is a protein preparation; therefore, it should be stored 2 - 8°C in a refrigerator (do not freeze) or store below 30°C. After reconstitution, it should not be refrigerated and must be administered within 3 hours. Avoid freezing to prevent damage to the diluent bottle.

Where can you get more information?

You can get more information from your doctor or pharmacist.

Name and address of the Sponsor

RECOMBINATE is manufactured by:

Baxalta US Inc
Westlake Village,
CA 91362, USA,

Distributed in Australia by:

Baxalta Australia Pty Ltd
1 Baxter Drive,
Old Toongabbie NSW 2148, Sydney

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